Exhibit G

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KIMBERLEE WILLIAMS, et al.	)	No. 2:11-cv-01754 (ES)
	)	(JAD) CIVIL ACTION
Plaintiffs,	)	
vs.	)	
BASF CATALYSTS LLC, et al.	)	
	)	
Defendants.	)	
	)	

DECLARATION OF EDGAR C. GENTLE, III, IN SUPPORT OF OUR APPOINTMENT AS LIEN ADMINISTRATOR

I, EDGAR C. GENTLE, III, hereby declare and state as follows:

My name is Edgar C. Gentle, III. I have practiced law for over thirty-five (35) years. I have participated in the creation and administration of mass torts settlements as an Escrow Agent or as a Claims Administrator since 1993. I have also served as Special Master and Mediator in a variety of mass tort cases and have routinely used my expertise to set the value of claims.

Our proposal and qualifications to provide lien resolution services are set out below.

A. Expertise and Experience

Exhibit A provides an overview of the settlement creation and lien resolution services that our firm provides. Our firm has a long storied history of lien resolution going back to MDL 926, the Breast Implant Settlement, created in 1993. In that case, we created one of the first global Medicare resolutions for a mass tort after the Defendants and I were sued in U.S. v. Baxter. See the 2003 Court Order in Exhibit B.

We successfully pioneered another large lien resolution case in the 18,000 Claimant Tolbert PCB Settlement. Refer to page 1261 of the Alabama Law Review Article in Exhibit C summarizing how we "tamed the sea of liens" for all 18,000 Claimants. These two global lien resolution settlements were carried out before many of our lien resolution competitors even existed.

From 1992 to 2014, I served as Special Master and Escrow Agent for the MDL 926 Global Breast Implant Settlement, paying $1.2 Billion in claims for 300,000 Claimants. From 2001 until 2003, I was Interim Financial Advisor for the Settlement Facility - Dow Corning Trust (the Dow Corning Breast Implant Settlement) overseeing the investment of over $1 Billion and providing tax and accounting support for the Settlement, during part of Dow Corning's Chapter 11 Bankruptcy.

I served as Settlement Administrator from 2015 to 2016 to facilitate three individual aggregate settlements for the New England Compounding Pharmacy, Inc, during the Chapter 11 Bankruptcy, involving individuals who were exposed to contaminated lots of a steroid compounded by New England Compounding Center. We have also been hired by multiple law firms to provide both government and private lien resolution services for these cases on an ongoing basis since 2015.

90% of our Firm's work involves the creation and administration of settlements. At any one time, we are working on about 30 settlements, and we have successfully facilitated the administration of settlements totaling approximately $3 Billion. Much of this work has involved lien resolution services.

For example, we were the lien resolution administrator in Hydroxycut. Our reference is Roger Orlando, Esq., The Orlando Firm, P.C., 404-373-1800, roger@OrlandoFirm.com, 315 W Ponce de Leon Avenue Suite 400, Decatur, GA 30030. Roger would be happy to advise you of the quality of our work. We also conduct all of the lien resolution services for all of the cases for prominent Plaintiffs Firm Andrews & Thornton. Anne Andrews, Esq., Andrews & Thornton, 949-748-1000, aa@andrewsthornton.com, 4701 Von Karman Avenue, Suite 300, Newport Beach, CA 92660 is a reference for our services there. We are also on the 3th round of an aggregate settlement involving a hip manufacturer, with each round involving about 250 Claimants. Our reference is Michael McGartland, Esq., McGartland Law Firm, PLLC, 817-332-9300, mike@mcgartland.com, 1300 South University Drive, Suite 500, Fort Worth, TX 76107. We have resolved personal injury liens for cases ranging from Chantix for 5 law firms, 4 train wrecks, the Total Body MDL, two zinc smelters, two fires (one factory and one prison), and chemical spills.

We are currently working on lien resolution services for approximately 20 settlements. The party that engages us tends to be a Judge or a lawyer who advocates for our selection. We currently work on a settlement for a mercury contamination case with a lawyer who has had a relationship with us for 20 years, which began with a PCB settlement. A train wreck settlement and a zinc smelter settlement resulted in a relationship we have had with a lawyer for about 15 years. Of the remaining cases, one law firm has had a relationship with us for 10 years, and the others have had a relationship between 1 and 5 years.

We have decades of experience integrating lien resolution with a multi-year claims resolution facility. For example, the Breast Implant Settlement lasted 25 years and the Tolbert PCB Settlement lasted 13 years. Our proven ability to timely and effectively communicate and respond to questions concerning lien resolution logistics and Claimant lien resolution status is proven by our track record and will be seconded by our references. Additional references are attached to Ed's resume in Exhibit D.

As depicted in Exhibit A, our goal is always to provide the Claimant with a holistic service, with our being accessible by an 800 number and email to the Claimant at any time to provide transparent and up-to-date information. We have provided lien resolution services in all 50 States.

Our firm has 7 lawyers, 4 accountants, and 6 assistants. Among them are 4 employees who have long and deep lien resolution experience, being Kip Benson, Jennifer Blankenship, Kathleen Clements and myself. Our resumes are in Exhibit D. I have been working in this field since 1993, along with Kip since 2004, Jennifer since 2011 and Kathleen since 2012.

B. Cost

By way of background, our initial proposal for government-related and all other medical lien resolution services was the lesser of (1) (i) verification of Medicare and Medicaid claims at $75 per eligible Claimant, (ii) resolution of Medicare and Medicaid claims at $250 per eligible Claimant and (iii) resolution of other governmental liens at $400 per eligible Claimant or (2) a 5% cap of the Claimants' total gross recovery under Parts A and B of the POD, which would have resulted in an approximate fee of $1,503,750.

After numerous conversations with Plaintiffs' Counsel regarding the settlement awards and the limited funds available, we have reduced our compensation to a flat fee of **$500,000** for the approximately 7,500 Part B claims for our services as summarized below in this declaration to provide lien resolution services for all governmental liens, as well as Medicare Part C and D liens. The fee is capped at $500,000 even if the number of Part B claims exceeds 7,500. Any other private medical insurance liens will only be resolved if the Claimant independently hires us to resolve such liens.

1. Verification of Medicare and Medicaid Claims

Receipt and review of the Claimant Benefits Questionnaire ("BQ"). Then, we will coordinate with the Claimants and the Medicare and Medicaid agencies to confirm which Claimants are eligible for Medicare and Medicaid benefits. Note that this Medicaid process is only for the state in which the Claimant resides.

2. Resolution of Medicare and Medicaid Claims

Once we have identified the Claimants that are eligible for Medicare and Medicaid benefits, we will work with the Claimants and Medicare and Medicaid agencies (including any other state Medicaid agency provided to us by a Claimant on the Benefits Questionnaire) to resolve any claims associated with this Settlement. We will attempt to resolve such claims on a global basis, if possible. If Medicare and/or Medicaid do not agree to resolution of claims for all eligible Claimants on a global basis, we will work with the Claimants and the Medicare or Medicaid agencies to resolve any claims for each eligible Claimant on an individual basis.

3. **Resolution of Other Governmental Liens as Well as Medicare Part C and D Liens**

We will work with the Claimants and other Governmental agencies, including TRICARE (DHA), the Department of Veterans Affairs and Indian Health Services, as well as Medicare Part C and D Providers, to resolve any claims on an individual basis.

C. Lien Resolution Services/Process

This process should begin as soon as possible to facilitate prompt Claimant payment.

Before the Claimants can be paid their Settlement amount, net of fees and expenses, liens, as set out in the Settlement Agreement, need to be resolved. Below, we describe the process.

1. **Lien Resolution Authorization Forms/Information.** Below is a brief description of our forms, attached hereto in Exhibit E, which will be utilized in this engagement.

   a. **Benefits Questionnaire** – A form that asks the Claimant to provide personal information such as name, contact information and SSN. It also asks detailed questions relating to any government medical benefits that the Claimant may have currently or have had in the past.

   b. **Proof of Representation Form** – For Medicare use only. This form indicates to Medicare that the Claimant has given them permission to release benefit information to us. After submitting this form to Medicare, we will be copied on all correspondence relating to lien resolution. We ask that the Claimant complete this form even if he/she believes that he/she does not receive this health benefit, as it can save time later in the process if we discover that the Claimant is entitled to this benefit.

   c. **Authorization to Disclose Health Information** – This is functionally the same as the Medicare Proof of Representation form described above, but is used for State administered Medicaid agencies, military agencies, private insurance agencies and any other medical insurance provider. One form will be needed for each entity from which the Claimant receives or received health benefits. We ask that the Claimant complete one of these forms even if he/she believes that he/she does not receive any of the types of health benefits listed above, as it can save time later in the process if we

discover that the Claimant is entitled to one or more of these benefits.

d. **Additional Information** – In addition to the forms listed above, we will need Claimant settlement information, including gross settlement amount, attorney fee percentage, total and final case expenses and settlement date. We need this information because some entities (including Medicare) require this information whether or not the entity has a lien against a Claimant's settlement and because this information is almost always required in order to negotiate reductions in medical liens.

2. **Resolution of Medicare, Medicaid, Other Governmental Liens, including TRICARE, the Department of Veterans Affairs, and Indian Health Services and Medicare Part C and D Plans.**

a. We will coordinate with the Claimants and the Medicare and Medicaid Agencies to confirm which Claimants are eligible for Medicare and Medicaid benefits.

b. Once we have identified the Claimants that are eligible for Medicare and Medicaid benefits, we will work with the Claimants and the Medicare and Medicaid Agencies to resolve any claims associated with this Settlement. We will attempt to resolve such claims on a global basis, if possible, with each Medicare Claimant maintaining an opt-out right.

c. If Medicare does not agree to resolution of claims for all eligible Claimants on a global basis, we will work with the Claimant and Medicare to resolve claims for each eligible Claimant on an individual basis. As discussed above, we will seek approval to work directly with Medicare's Special Project Unit. If we cannot work with Special Projects, we will contact the Benefits Coordination and Recovery Contractor ("BCRC") directly to verify Medicare eligibility for each Claimant using the social security number and date of birth provided by each Claimant on our BQ. We will open cases with the BCRC and use Medicare's online portal to submit representation documentation, check for case updates, dispute unrelated charges and submit final settlement information.

d. If Medicare and/or Medicaid do not agree to resolution of claims for all eligible Claimants on a global basis, we will work with the Claimants and the Medicare and/or Medicaid agencies to resolve claims for each eligible Claimant on an individual basis.

e. We will work with the Claimants and other governmental agencies, including TRICARE, the Department of Veterans Affairs, and Indian Health Services, as well as Medicare Part C and D Plans to resolve any claims on an individual basis.

3. Possible Global Government Lien Resolution for Smaller Claims.

We have found that Medicare and State Medicaid Agencies are open to a fixed percent of the recovery, as an optional Settlement for the Claimants. We design this option, so that the Claimants can take it (settle) or leave it (go through the granular lien resolution process). This process has been successfully utilized in cases involving breast implants, PCBs, hip implants, factory fires and nutrients, for example. We will determine if a global settlement is feasible, otherwise, the Claimants' Medicare liens will be resolved individually.

4. Reporting/Status Updating

In carrying out lien resolution administration, we work from a master Excel spreadsheet, that has columns for each type of lien with the status, which we update on a real time basis. We also have telephone consultants that field Claimant questions on a real time basis, and we often set up a special email address for a given settlement to do the same thing.

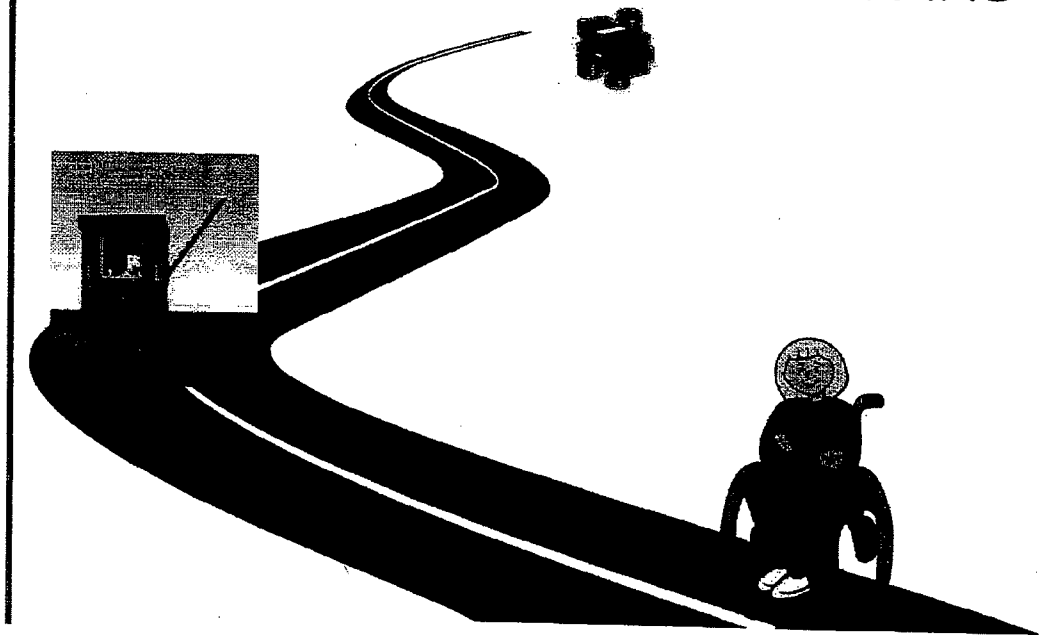
Status reports provided by lien type and Claimant numbers are provided as frequently as requested but are usually given on a monthly basis. A unique identifier or Claimant specific format is available.

I declare under penalty of perjury that the foregoing is true and correct. Executed on April 20, 2020.

Edgar C. Gentle, III

EXHIBIT A

THE ROAD TO VICTIM SETTLEMENT RECOVERY: SETTLEMENT CREATION AND LIEN RESOLUTION



Ed Gentle

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Suite 100

Hoover, Alabama 35244

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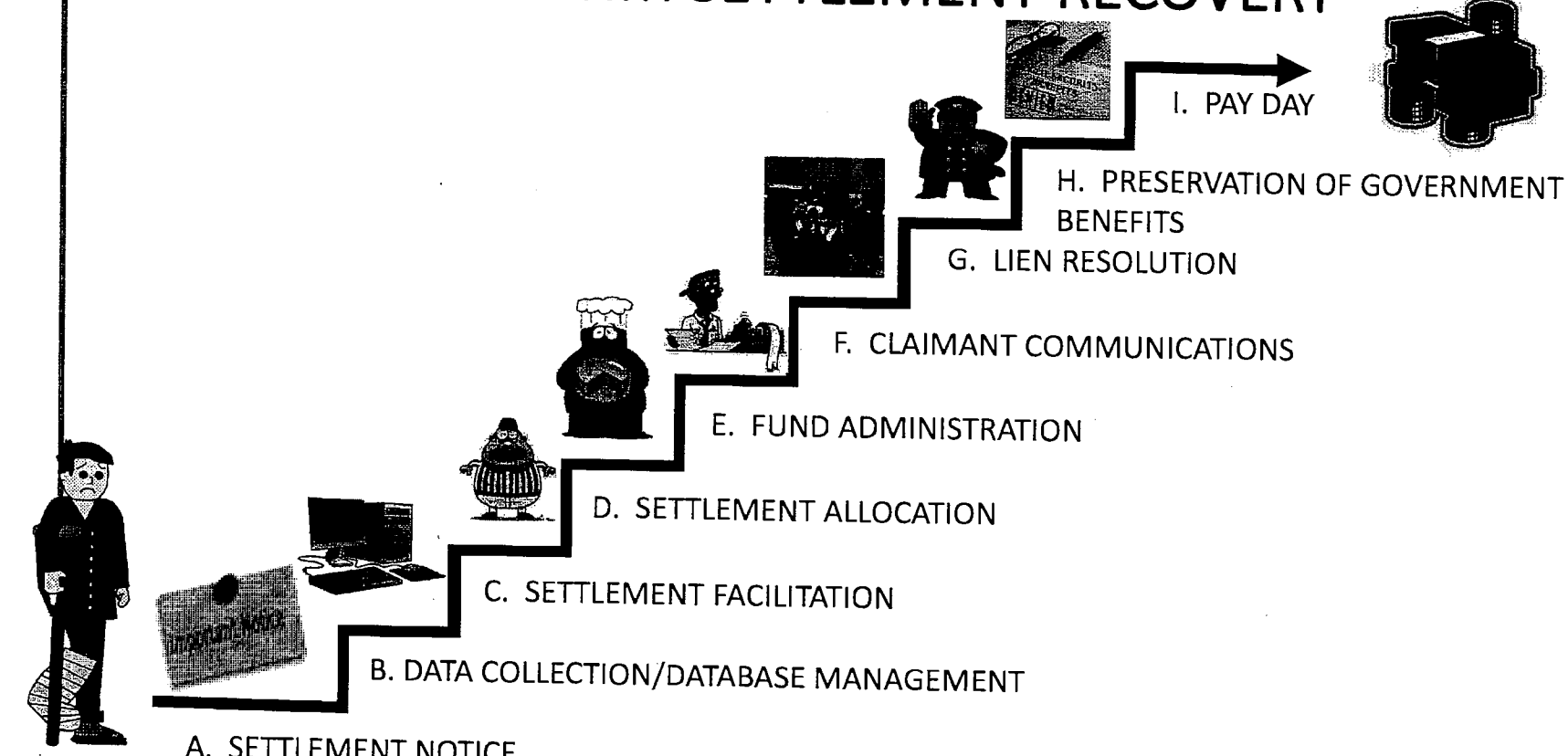
(205) 960-2533 (cell)

(205) 716-3000 (office)

GENTLE TURNER SEXTON & HARBISON, LLC

THE ROAD TO VICTIM SETTLEMENT RECOVERY



FIRM EXPERTISE

Gentle, Turner, Sexton & Harbison, LLC specializes in the creation and administration of Class Action and Aggregate Mass Tort Settlements. We are experts in all aspects of settlement administration, from mediating a settlement, the provision of Claimant notice, to the design and implementation of Claimant payment programs, including lien resolution. We have orchestrated wide-reaching remedies beyond simple payment programs, including global MDL Settlements for product defects and drugs, large tax and other government payment refund settlements, the remediation of toxic contamination, and administration of medical monitoring programs and health clinics. Our experience and expertise allows us to provide a cost-effective remedy that is both holistic and heuristic.

We were founded in 1989 by Ed Gentle, who has comprehensive experience in the administration of dozens of mass settlements where he has served as a Special Master and/or Claims Administrator. Ed has been designing and paying out Mass Tort Settlements for more than 20 years. He has also provided financial and business advice and mediation services to both Courts and counsel in complex Mass Tort Litigation.

To date, we have administered more than $3 billion in Settlement Funds, processed more than 500,000 claims, published over 500,000 notices, and answered more than 200,000 Claimant telephone calls. We are a skilled team of specialized experts in all aspects of Mass Tort Settlement Administration.

- Escrow Agent and Special Master for the $2B Global MDL 926 Breast Implant Revised Settlement Program, with over 200,000 Claimants.
- Special Master for the Spelter, West Virginia Smelter Medical Monitoring and Property Remediation Settlement
- Claims Administrator for 3 Monsanto-Pharmacia PCB Contamination Settlements, including the $300 million Tolbert Settlement, which has a personal injury and property program, a Medical Clinic and College Scholarships
- Claims Administrator and Special Master for 250,000 Jefferson County, Alabama Occupational Tax Refund Judgment Claimants.
- Other settlements include factory sites, defective hip devices, train wrecks, drinking water contamination, retirement plans and drugs

A. **SETTLEMENT NOTICE:** We have provided notice to Claimant groups ranging from 300 to 30M, using all possible forms of notice.

B. **DATA COLLECTION/DATABASE MANAGEMENT -** We develop and distribute all forms needed from Claimants and maintain an informational database for a mass case, and its eventual settlement. Our data collection process can be tailored for any situation or any case type. Information is kept electronically and in hard copy form for easy access.

C. **SETTLEMENT FACILITATION -** We provide mediation services that have resulted in settlements big and small. We are experts at a bottoms up mediation, scoring each claimant on a grid, and thereby determining the settlement "sweet spot".

D. **SETTLEMENT ALLOCATION SERVICES -** By utilizing medical records or analyzing other data points, we can develop a customized system for fairly allocating settlement funds to each Claimant. We communicate with and educate Claimants regarding the allocation system and can provide an appeal process through which Claimants will have the opportunity to challenge settlement allocation decisions. We can handle mass tort or individual cases.

E. **FUND ADMINISTRATION -** We establish and maintain Qualified Settlement Funds through which settlement funds will be distributed to all Parties, when applicable. We provide financial reports required by the Court. Additionally, we prepare all tax returns and prepare and distribute 1099 forms when appropriate.

F. **CLAIMANT COMMUNICATIONS SERVICES** - Communicating with Claimants is a service that is always included in our scope of work. We set up a toll-free information lines and live representatives to handle Claimant calls during regular business hours. When speaking with Claimants, we strive to educate them on the settlement process and the lien resolution process, providing realistic timelines.

G. **LIEN RESOLUTION -** We navigate the dynamic and confusing Lien Resolution process for you. We implement efficient work flow processes to get timely lien resolution for Claimants, and we ensure that your Claimants pay only their equitable share of health care liens. Our expertise includes: Medicare, Medicaid, Military insurance, VA health care and private insurance.

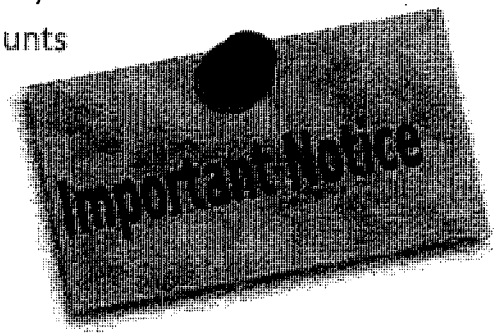
H. **PRESERVATION OF GOVERNMENT BENEFITS -** A universal Claimant concern is preservation of ongoing government benefits. We advise Claimants on their options to preserve benefits during and after the settlement payment process. Frequent government benefits to be preserved are Medicaid, SSI, housing assistance, and state administered medical assistance.

I. **PAY DAY - $**

A. SETTLEMENT NOTICE

Settlement Legal Notification: We offer customized and cost-effective notice plans to meet the individual details and budgets of each Settlement. We work hand-in-hand with the principals of each Settlement to develop a balanced and adaptive solution to legal notice needs from planning and proof-reading to providing plain language suggestions or suggestions based on past experience. Our firm oversees all aspects of notice plan implementation, including mailings, publication, and the management of a website and dedicated e-mail accounts to maintain connectivity with Claimants in the digital age. Ed Gentle often provides both Court and counsel with expert advice and opinion testimony on the design and efficacy of notice in complex settlements. We provide related services including the following:

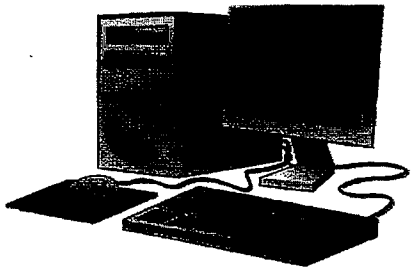
- Postcard Notice
- Design of Claim Forms for practicality and efficiency (manual or e-completion)
- Management of customized Claimant data, such as individual damage accounts
- Direct mail
- Email
- Newspaper advertising
- Custom website design and maintenance



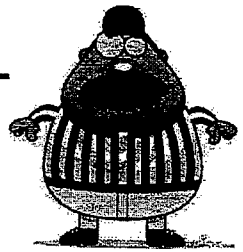
B. DATA COLLECTION/DATABASE MANAGEMENT

Processing Claimant Settlement Data: One of the key aspects of the administration of a successful and efficient Settlement is the management of an accurate database of Claimant information. During the initial stages of a Settlement, this valuable information is often scattered across multiple locations and recorded in many formats. Our team will work with almost any data format under even the most stringent of deadlines. We are experts in the efficient and timely management of Claimant data, and use our advanced technical resources to produce a database that includes the following items, as well as other pertinent information on a case-by-case basis:

- Claimant identification, including anonymous numeric identifiers to protect confidential information
- Management of multiple file types, data formats and layouts
- Creation of a single master database of all eligible Claimants
- Removal of duplicate claims
- Efficient formatting of mailing lists
- Skip-tracing of missing Claimants
- Address verification through the post office and Internet data search engines
- The assessment of Claimant eligibility
- Insurance benefits information (see Lien Resolution)



C. SETTLEMENT FACILITATION

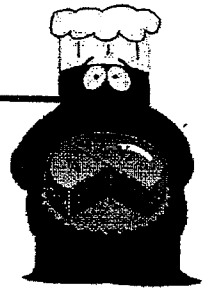


We have successfully mediated the settlements for from 1 to 10,000 claimant cases, at total settlement amounts ranging from $300,000 to $70,000,000

Because of our expertise in settlement payment modeling, we are able to quantify, before mediation, the minimum amount necessary to fairly compensate claimants. To do so, we mine the data collected in Part B, to develop a payment matrix with plaintiffs' counsel and run the numbers.

We often mediate in tandem with the Court to successfully settle a mass case, including The Perrine DuPont Zinc Smelter Settlement in Clarksburg, West Virginia, and the Total Body MDL with the Honorable R. David Proctor, who now sits on the MDL Panel.

D. SETTLEMENT ALLOCATION SERVICES



By utilizing medical records and analyzing other data, we develop a matrix customized to the case, normally based on a points-based rating system, for fairly and objectively allocating settlement funds for each Claimant. This includes adding points for extenuating circumstances or deducting points for contributing injury factors.

Our team reviews medical records thoroughly, if applicable, and makes an assessment of the comparative level of damages to Claimants, to establish the range of injuries in a group settlement. Once the range is established, we usually categorize each Claimant in a base group, and, based on agreed, objective, specific individual circumstances, make adjustments to the allocation.

After initial allocations, we draft settlement information packets for each Claimant, so that they are informed of how potential settlement awards are allocated per person. To maintain transparency, we also provide a range of settlements for the group of Claimants, with confidential information redacted for privacy. We provide phone support to answer questions Claimants may have about their settlement, so that they can make an educated, informed decision on whether to settle.

Additionally, we usually provide a settlement appeal process through which plaintiff counsel and their Claimants will have the opportunity to challenge settlement allocation decisions.

We so handle mass torts, class, aggregate or individual cases.

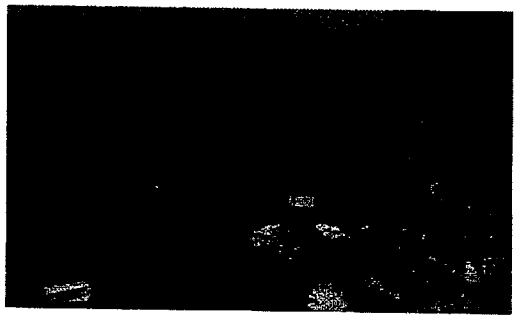
E. SETTLEMENT FUND ADMINISTRATION

Our team of attorneys, CPAs and support staff proficiently manage Settlement Funds in safe investment vehicles, while satisfying IRS and other tax reporting requirements, and meeting generally accepted accounting principles and fiduciary reporting requirements.

After providing an explanation of Claimant benefits and potential tax liability to each Claimant, we can remit payment in any of the following methods: check, coupon, certificate, pre-paid cards, wire transfer, or a combination of any of the above methods. We are also experts in providing in-kind Claimant relief, including Property Remediation, Medical Monitoring, Medical Clinics and College Scholarships. We take protective measures to ensure the security and efficiency of our Claimant distributions.

In connection with this process, we provide the following services:

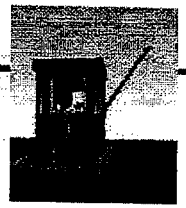
- Explanation of Claimant benefits
- Reconciliation of accounts
- Tax reporting
- Settlement Fund investment management
- Settlement Fund tax reporting
- 1099 tax reporting where applicable
- IRS and other tax reporting compliance
- Multiple payment distribution methods
- Regular periodic accountings of Settlement Funds under our management to Counsel for the Plaintiffs and the Court



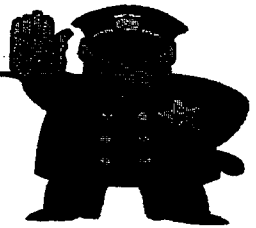
F. CLAIMANT COMMUNICATIONS SERVICES

Our staff of telephone support personnel is very experienced in handling Claimant questions and explaining the details of individual Settlements. We have fielded more than 200,000 Claimant telephone calls for over $3 billion in settlements. Additionally, for Claimants who prefer written correspondence, we are very efficient in analyzing and answering their questions and providing a prompt and attentive answer. For every Settlement, we develop a customized list of frequently asked questions and answers, which are provided to Claimants and posted on the Settlement website. Our services include:

- Toll-free information lines
- Live operators during business hours
- Automated responses when applicable
- Foreign language services
- Customized Claimant communications statistics reporting to the Court and Settlement principals



G. LIEN RESOLUTION SERVICES



We are here to assist you in navigating the complicated regulations regarding medical lien resolution. We have cultivated relationships with many government and private insurers to make the lien process as efficient and seamless as possible.

We begin the lien resolution process by having each Claimant complete a detailed Benefits Questionnaire, a release form for Medicare and a general medical release form. Each of these documents is easy to complete. The forms are described below.

- **Benefits Questionnaire** – A form that asks the Claimant to provide personal information such as name, contact information and SSN and injury information. It also asks questions relating to any government and private insurance benefits that the Claimant may have currently or have had in the past. This form can be tailored for any settlement type.
- **Proof of Representation Form** – For Medicare use only. This form shows Medicare that the Claimant has given them permission to release benefit information to us. After submitting this form to Medicare, we will be copied on all information relating to the Claimant's lien resolution. If the Claimant is deceased, additional information will be required.
- **Authorization to Disclose Health Information** – This is functionally the same as the Medicare Proof of Representation form described above, but is used for state administered Medicaid agencies, military agencies, VA agencies and private insurers. Florida and Texas Medicaid will require their own release form. Some military agencies will require an additional medical authorization as well as other forms.

Once we receive all of the completed forms back from the Claimants, we will review everything and enter all of the information into a database. For any additional information we need or any information omitted by the Claimants, we will work with the Claimant directly to get everything necessary to complete the documentation process.

Once the settlement becomes viable, we will immediately contact each agency to begin the lien resolution process.

We are sensitive to the pressing need to resolve lien claims quickly and fairly, and provide claimants and their counsel realistic lien resolution time frames.

H. PRESERVATION OF CLAIMANT GOVERNMENT BENEFITS

Working with a settlement administration partner, Tort IQ, using online technology, we identify government benefits received by each Claimant, including SSI and Medicaid, analyze the impact of the settlement on the Claimant's benefit eligibility, recommend to the Claimant how best to preserve the benefits while enjoying the settlement, and document that advice. Based on providing this service for the transvaginal mesh case, it appears that mass tort Claimants have a higher incidence of government benefits than the general public, making these services critical.

What mass tort attorneys are thinking…

Liability

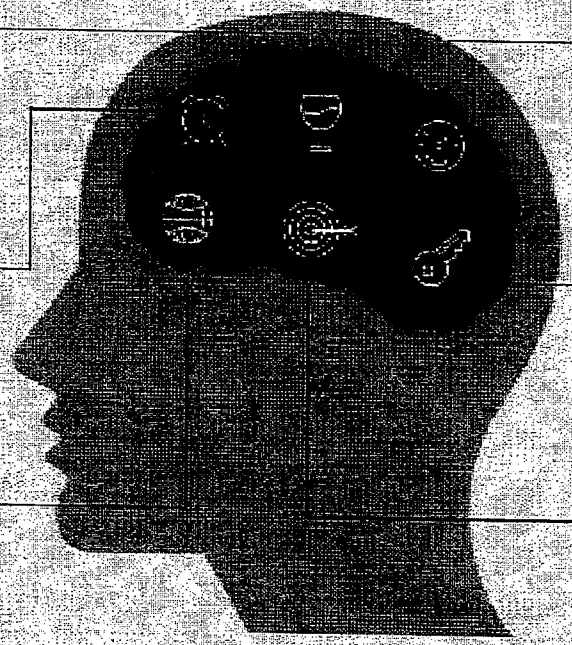
Mass tort and single event attorneys are concerned about claimants losing government benefits without the proper education.

Speed

Attorneys want claimants informed about the impact of their settlements on benefit eligibility but are concerned about the time involved in doing so.

Uniformity

Attorneys want advice delivered in a uniform and systematic way.



Documentation

Is the advice given to claimants documented? How do you know what was said to each claimant?

Objectivity

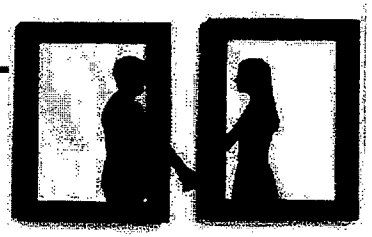
Are claimants given objective advice? Or, are financial advisors selling products?

Scalable

How do you provide accurate individualized information to masses of claimants?

Tort

I. THE SYNERGY OF COMBINING SETTLEMENT ADMINISTRATION AND LIEN RESOLUTION



Our firm is fully capable and staffed to handle both Settlement Administration and Lien Resolution. While these are two separate functions, combining the functions is efficient for you and your Claimants for many reasons.

We have had the opportunity to work with some of our competitors in the past. We have found that they do not often speak with the Claimants directly. Generally, their fees do not include contact with the Claimant to discuss the lien or get approval for the resolution of the Claimant's lien, and there is an additional charge for Claimant communications. With our services, Claimant contacts are routinely made, and there is no special charge.

Combining Lien Resolution services with Settlement Administration services improves accuracy and efficiency by eliminating third party communications and ensuring that Settlement information and individual Claimant expenses are correctly reported to insurers. It also allows us to effectively communicate with your Claimants to be able to provide them with instructions and guidance on both their lien resolution and settlement payment timeline without frustrating the Claimant by directing them to another entity for answers.

We provide Claimants with informational documentation containing FAQs and a step by step process for lien resolution and settlement administration, and realistic payment timelines. Educating the Claimant ahead of time on our processes and the payment timeline helps alleviate their frustrations of waiting/planning for future payments, and reduces the volume of Claimant communications for both your firm and ours.

We will get involved! If we get unfavorable or unexpected results from a lien dispute or appeal, we won't hesitate to call an agency to get more information or to move an appeal to the next level, including litigation. We will also contact the Claimant to get further explanations, to facilitate lien resolution. We want the best results for the Claimants.

We have the ability to issue payments on demand. Generally, we process payments in batches. However, if circumstances arise, we issue payments outside of a batch, depending on the terms of the Settlement Agreement or Qualified Settlement Fund.

EXHIBIT B

United States v. Baxter Int'l, Inc.

United States Court of Appeals for the Eleventh Circuit
September 15, 2003, Decided ; September 15, 2003, Filed
No. 01-16782

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UNITED STATES OF AMERICA, Plaintiff- Appellant, versus BAXTER INTERNATIONAL, INCORPORATED; BAXTER HEALTHCARE CORPORATION, et al., Defendants-Appellees, PLAINTIFFS' STEERING COMMITTEE, Defendant-Intervenor-Appellee.

Subsequent History: US Supreme Court certiorari denied by *Baxter Int'l Inc. v. United States, 542 U.S. 946, 124 S. Ct. 2907, 159 L. Ed. 2d 828, 2004 U.S. LEXIS 4734 (2004)*

Related proceeding at In re Crawford, 2012 U.S. Dist. LEXIS 45423 (E.D. Mich., Mar. 30, 2012)

Related proceeding at Juris v. Inamed Corp., 685 F.3d 1294, 2012 U.S. App. LEXIS 13841 (11th Cir. Ala., 2012)

Prior History: [**1] Appeal from the United States District Court for the Northern District of Alabama. D. C. Docket No. 00-00837-CV-N-S. Edwin L. Nelson, Judge.

In re Silicone Gel Breast Implants Prods. Liab. Litig., 174 F. Supp. 2d 1242, 2001 U.S. Dist. LEXIS 19354 (N.D. Ala., 2001)

Disposition: Affirmed in part, reversed and remanded in part.

Core Terms

payment, plan, insurance, claim, self-insured, primary, pay, statute, reimbursement, service, entity, liability, regulate, item, received, conditional, interpretation, promptly, required, expected, settlement, party, policy, statutory, pleading, class, district court, damage, knowledge, agency's

Case Summary

Procedural Posture

Appellee manufacturers of breast implants settled a class action brought by appellee patients who suffered illnesses traceable to implants, and appellant United States intervened to recover under *42 U.S.C.S. § 1395y(b)* for amounts paid on behalf of patients who were Medicare beneficiaries. The United States appealed the order of the United States District Court for the Northern District of Alabama which dismissed the United States' claims.

Overview

The United States contended that *§ 1395y(b)* permitted it to recover from the manufacturers Medicare payments to patients whose treatment costs for implant-related illnesses were payable by the manufacturers, or their insurers, under the class action settlement. The manufacturers maintained that the United States failed to identify the patients who received Medicare benefits and, in any event, *§ 1395y(b)* did not provide any basis for recovery of the payments from the manufacturers. The appellate court first held that the United States sufficiently identified the class of relevant patients, since the identity of specific patients involved in the settlement was within the exclusive control of the manufacturers. Further, the Medicare payments were not unconditional but rather secondary to primary coverage under *§ 1395y(b)*, and the manufacturers were self-insurers subject to *§ 1395y(b)* based on ex ante arrangements to assume legal liability. Also, the manufacturers had at least constructive knowledge of the Medicare payments for subrogation purposes, and the manufacturers were entities which received recoverable payments from primary plans within the meaning of *§ 1395y(b)*.

Outcome

The order dismissing the United States' claims was affirmed with regard to claims against a settlement escrow agent, but the order was otherwise reversed and the case was remanded for further proceedings.

LexisNexis® Headnotes

Insurance Law > ... > Policy Interpretation > Reasonable Expectations > General Overview

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Medicare > Coverage > General Overview

Public Health & Welfare Law > Social Security > Medicare > Medicare Act Interpretation

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN1 In a nutshell, *42 U.S.C.S. § 1395y(b)* declares that, under certain conditions, Medicare will be the secondary

rather than primary payer for its insureds. Consequently, Medicare is empowered to recoup from the rightful primary payer (or from the recipient of such payment) if Medicare pays for a service that was, or should have been, covered by the primary insurer. Although the statute is structurally complex, a complexity that has produced considerable confusion among courts attempting to construe it, the statute's function is straightforward. If payment for covered services has been or is reasonably expected to be made by someone else, Medicare does not have to pay. In order to accommodate its beneficiaries, however, Medicare does make conditional payments for covered services, even when another source may be obligated to pay, if that other source is not expected to pay promptly.

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN2 See 42 U.S.C.S. § 1395y(b)(2)(A)-(B).

Insurance Law > ... > Alternative Risk Transfers > Self Insurance > General Overview

Public Health & Welfare Law > Social Security > Medicare > General Overview

HN3 Under 42 C.F.R. § 411.50(b), a self-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier. Under 42 C.F.R. § 411.21, a plan is defined as any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness.

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN4 42 U.S.C.S. § 1395y(b)(3)(A) provides for a private right of action, with double damages available, if a primary plan fails to provide for primary payment (or appropriate reimbursement) in accordance with the Medicare Secondary Payer regulations.

Public Health & Welfare Law > Social Security > Medicare > General Overview

HN5 See 42 C.F.R. § 411.24.

Public Health & Welfare Law > Social Security > Medicare > General Overview

HN6 42 C.F.R. § 411.21 defines "prompt" or "promptly," when used in connection with third-party payments, to mean payment within 120 days after receipt of the claim.

Insurance Law > ... > Policy Interpretation > Reasonable Expectations > General Overview

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Medicare > Coverage > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN7 The Omnibus Budget Reconciliation Act of 1980, Pub.L. No. 96-499, § 953, 94 Stat. 2599, amended the Medicare Act to provide that Medicare payments may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made (as determined in accordance with regulations) under an automobile or liability insurance policy or under no fault insurance.

Insurance Law > ... > Policy Interpretation > Reasonable Expectations > General Overview

Insurance Law > Claim, Contract & Practice Issues > Subrogation > General Overview

Insurance Law > Claim, Contract & Practice Issues > Subrogation > Contractual Subrogation

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Medicare > Coverage > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN8 The Deficit Reduction Act of 1984 (DERFA) confers on the government a direct right of action to recover its payments from any entity which would be responsible for payment under a law, policy, plan, or insurance, and provides that the government would be subrogated to the right of any individual or entity to receive payment. DERFA also modifies the original wording of the secondary payment provision by adding the modifier "promptly," so that the pivotal phrase dictates that a Medicare payment may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made promptly with respect to such item or service, under a workman's compensation plan or plan of the United States or a state or under an automobile or liability insurance policy or plan (including a self-insured plan) or no-fault insurance. In the Omnibus Budget Reconciliation Act of 1980, Pub.L. No. 96-499, 94 Stat. 2599, Congress adds the private right of action for double damages codified at 42 U.S.C.S. § 1395y(b)(3)(A). It also adds the cross-reference to that section in § 1395y(b)(2)(B)(ii), which enables the government to collect double damages in accordance with the new private right of action.

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

Civil Procedure > Dismissal > Involuntary Dismissals > Failure to State Claims

Civil Procedure > Appeals > Standards of Review > De Novo Review

HN9 An appellate court reviews a district court's grant of a motion to dismiss for failure to state a claim de novo.

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

HN10 A motion to dismiss a complaint in intervention is reviewed under the same standard applicable to consideration of a motion to dismiss the original plaintiffs' complaint.

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

Civil Procedure > ... > Pleadings > Complaints > Requirements for Complaint

Civil Procedure > Pleading & Practice > Pleadings > Rule Application & Interpretation

HN11 In evaluating the sufficiency of a complaint under Fed. R. Civ. P. 12(b)(6), courts must be mindful that the Federal Rules of Civil Procedure require only that the complaint contain a short and plain statement of the claim showing that the pleader is entitled to relief. Fed. R. Civ. P. 8(a).

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

Civil Procedure > Dismissal > Involuntary Dismissals > Failure to State Claims

HN12 In applying Fed. R. Civ. P. 12(b)(6), a complaint should not be dismissed for failure to state a claim unless it appears beyond a doubt that the complainant can prove no set of facts in support of his claim which would entitle him to relief.

Civil Procedure > ... > Pleadings > Complaints > Requirements for Complaint

Civil Procedure > Pleading & Practice > Pleadings > Rule Application & Interpretation

HN13 Because the Federal Rules of Civil Procedure embody the concept of liberalized notice pleading, a complaint need contain only a statement calculated to give a defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests.

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

HN14 The threshold of sufficiency to which a complaint is held at the motion-to-dismiss stage is exceedingly low. For better or for worse, the Federal Rules of Civil Procedure do not permit district courts to impose upon plaintiffs the burden to plead with the greatest specificity they can.

Civil Procedure > Pleading & Practice > Pleadings > Rule Application & Interpretation

Civil Procedure > Parties > Intervention > General Overview

HN15 Fed. R. Civ. P. 24 requires merely that an intervenor's petition shall state the grounds for intervention and shall be accompanied by a pleading setting forth the claim or defense for which intervention is sought. Fed. R. Civ. P. 24(c). The determination of whether the proposed intervenor's complaint states a cause of action is controlled by the general rules on testing a pleading; the factual allegations of the complaint are assumed to be true and the pleading is construed liberally in support of the pleader.

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

HN16 At the pleading stage, general factual allegations of injury resulting from a defendant's conduct may suffice, for on a motion to dismiss courts presume that general allegations embrace those specific facts that are necessary to support the claim.

Civil Procedure > ... > Pleadings > Complaints > Requirements for Complaint

Civil Procedure > Pleading & Practice > Pleadings > Rule Application & Interpretation

HN17 The liberal notice pleading of Fed. R. Civ. P. 8(a) is the starting point of a simplified pleading system. Rule 8(a) establishes a pleading standard without regard to whether a claim will succeed on the merits. Indeed, it may appear on the face of the pleadings that a recovery is very remote and unlikely but that is not the test.

Civil Procedure > Pleading & Practice > Pleadings > Rule Application & Interpretation

HN18 Courts typically allow a pleader an extra modicum of leeway where the information supporting the complainant's case is under the exclusive control of the defendant.

Civil Procedure > Special Proceedings > Class Actions > Notice of Class Action

Civil Procedure > ... > Class Actions > Prerequisites for Class Action > General Overview

HN19 In a class action, it is sufficient that a complaint generally give a defendant notice of the nature and scope of the plaintiffs' claims; it is not necessary that the class representatives plead evidence or otherwise meet any burden beyond the minimal Fed. R. Civ. P. 8 standard.

Civil Procedure > Sanctions > Baseless Filings > General Overview

HN20 See Fed. R. Civ. P. 11(b).

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

Civil Procedure > ... > Pleadings > Heightened Pleading Requirements > General Overview

Civil Procedure > ... > Pleadings > Heightened Pleading Requirements > Fraud Claims

HN21 Where Fed. R. Civ. P. 9 is implicated, plaintiffs must plead not only the general nature of their injuries but also the specifics of how and when they were injured. By implication, then, a complaint governed by the ordinary standard of Fed. R. Civ. P. 8 need not allege the particulars of each instance of injury in order to survive a motion to dismiss.

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN22 See 42 U.S.C.S. § 1395y(b)(2)(A), (B).

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > Social Security > Medicare > Medicare Act Interpretation

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN23 Under 42 U.S.C.S. § 1395y(b)(2), Medicare would endeavor not to pay where a primary insurance plan has paid or is expected to pay promptly, but any payment that Medicare does make is secondary and is subject to reimbursement from sources of primary coverage under the statute.

Administrative Law > Judicial Review > Standards of Review > Deference to Agency Statutory Interpretation

Governments > Legislation > Interpretation

HN24 Where statutory ambiguity exists, the reasonable interpretation of the agency charged with implementing the statute is entitled to judicial deference.

Governments > Legislation > Interpretation

HN25 The first step in the two-step agency deference review is to determine whether Congress has directly and unambiguously spoken to the precise question at issue. If so, a court's inquiry is at an end, for it must honor Congress 's clearly expressed intent. Determining whether Congress has unmistakably addressed the issue requires looking at the particular statutory language at issue, as well as the language and design of the statute as a whole. If Congress has not directly addressed the issue, or the statutory provision is ambiguous, the court comes to the second stage of the review: whether the agency's construction of the statute is reasonable and consistent with congressional intent. If so, the court must accede to it. The consistency of an agency's interpretation over time is a factor in determining the level of deference due.

Public Health & Welfare Law > Social Security > Medicare > General Overview

HN26 See 42 C.F.R. § 411.21.

Public Health & Welfare Law > Social Security > Medicare > General Overview

HN27 See 42 U.S.C.S. § 1395y(3)(A)(i).

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > Social Security > Medicare > Medicare Act Interpretation

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN28 Payments made by Medicare on behalf of patients are conditioned upon reimbursement if the patients later recover from one of the primary sources enumerated in 42 U.S.C.S. § 1395y(b)(2)(A).

Insurance Law > ... > Alternative Risk Transfers > Self Insurance > General Overview

Insurance Law > Industry Practices > General Overview

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN29 For purposes of 42 U.S.C.S. § 1395y(b), regulations define a "plan" of insurance as including any arrangement, oral or written, by one or more entities, to assume legal liability for injury or illness. 42 C.F.R. § 411.21. Inclusion of the term "oral" suggests an intent to reach informal, ad hoc arrangements in addition to traditional insurance policies; obviously, no standard insurance company issues coverage verbally. In addition, the regulations provide the following definition of a "self-insured" plan: a self-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier. 42 C.F.R. § 411.50(b).

Insurance Law > ... > Alternative Risk Transfers > Self Insurance > General Overview

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN30 The United States Department of Health and Human Services expressly defines a "liability insurance payment" for purposes of 42 U.S.C.S. § 1395y(b) to include a payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan. 42 C.F.R. § 411.50(b).

Insurance Law > ... > Alternative Risk Transfers > Self Insurance > General Overview

Insurance Law > Industry Practices > General Overview

Public Health & Welfare Law > Social Security > Medicare > General Overview

HN31 An absolute requirement for a self-insurance plan that funds be set aside is plainly inconsistent with the thrust of regulations: that a self-insurance plan encompasses any arrangement, even an oral one, to assume such risks, 42 C.F.R. § 411.21; and that it encompasses a combination of deductibles and insurance policies, which in common experience often do not include a set-aside of funds. 42 C.F.R. § 411.50(b).

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN32 See 42 U.S.C.S. § 1395y(b)(2)(B)(iii).

Civil Procedure > Preliminary Considerations > Federal & State Interrelationships > General Overview

Civil Procedure > ... > Federal & State Interrelationships > Federal Common Law > General Overview

Governments > Legislation > Interpretation

HN33 Courts presume that Congress legislates against the backdrop of established principles of state and federal common law, and that when it wishes to deviate from deeply rooted principles, it will say so.

Contracts Law > Standards of Performance > Assignments > General Overview

Governments > Courts > Common Law

Insurance Law > Claim, Contract & Practice Issues > Subrogation > General Overview

Torts > Procedural Matters > Settlements > General Overview

HN34 It is well established at common law that a tortfeasor that pays a settlement to a claimant with knowledge, actual or constructive, that another entity has a subrogation claim against the proceeds is not insulated from suit by the subrogee by virtue of the incorrect payment.

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN35 If tortfeasors had either knowledge or constructive knowledge that recipients of funds they were paying out had received medical treatment for which Medicare already paid, then the tortfeasors are liable to reimburse the government pursuant to 42 U.S.C.S. § 1395y(b)(2)(B)(iii).

Civil Procedure > ... > Pleadings > Heightened Pleading Requirements > General Overview

Civil Procedure > ... > Pleadings > Heightened Pleading Requirements > Fraud Claims

Civil Procedure > Pleading & Practice > Pleadings > Rule Application & Interpretation

HN37 Defendants' knowledge is an element that may be averred generally.

Evidence > Inferences & Presumptions > General Overview

HN36 A party that willfully blinds itself to a fact can be charged with constructive knowledge of that fact.

Labor & Employment Law > Employer Liability > Third Party Insurers

Public Health & Welfare Law > Social Security > Medicare > General Overview

HN38 See 42 C.F.R. § 411.24(i).

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN39 The government must prove at least constructive knowledge to prevail in a claim for double payment under either 42 U.S.C.S. § 1395y(b)(2)(B)(ii) or (iii).

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN40 See 42 U.S.C.S. § 1395y(b)(2)(B)(ii).

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN41 42 U.S.C.S. § 1395y(b)(3)(A) establishes a private cause of action for double damages in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with § 1395y(b)(1), (2)(A).

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Medicare > Coverage > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

Public Health & Welfare Law > ... > Providers > Types of Providers > Physicians

HN42 See 42 U.S.C.S. § 1395y(b)(2)(B)(ii).

Governments > Legislation > Interpretation

HN43 Under the doctrine of ejusdem generis, when an enumeration of specific things is followed by some more general word or phrase, then the general word or phrase will usually be construed to refer to things of the same kind or species as those specifically enumerated.

Healthcare Law > Healthcare Litigation > Actions Against Healthcare Workers > General Overview

Healthcare Law > Healthcare Litigation > Actions Against Healthcare Workers > Doctors & Physicians

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Medicare > Providers > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

Public Health & Welfare Law > ... > Providers > Types of Providers > Physicians

HN44 The regulation implementing 42 U.S.C.S. § 1395y(b)(2)(B)(ii), 42 C.F.R. § 411.24(g), lists as examples of entities liable as recipients: a beneficiary, provider, supplier, physician, attorney, state agency, or private insurer that has received a third party payment. This list is broader than that furnished by the statute, but even the agency's examples all are entities that would be receiving payment under a claim of right or entitlement to retain it.

Insurance Law > Claim, Contract & Practice Issues > Group Policies > General Overview

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN45 42 U.S.C.S. § 1395y(b)(2)(B)(ii) provides that the government may not recover from a third-party administrator under the relevant clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated.

Insurance Law > ... > Alternative Risk Transfers > Self Insurance > General Overview

Public Health & Welfare Law > Social Security > Medicare > General Overview

Public Health & Welfare Law > ... > Providers > Reimbursement > Medicare Secondary Payer Act

HN46 42 C.F.R. § 411.24(g) lists an insurer as an example of a party that may be liable as having received payment. 42 U.S.C.S. § 1395y(b) treats self-insured entities as insurers.

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Judges: Before TJOFLAT, ANDERSON and CUDAHY *, Circuit Judges.

Opinion by: ANDERSON

Opinion

[*872] ANDERSON, Circuit Judge:

This case grows out of the 1995 settlement of a class-action products liability suit against manufacturers of silicone breast implants. The settlement resulted in the creation of a reimbursement mechanism by which several settling manufacturers agreed to cover certain health care expenses incurred by or on behalf of qualified members of the plaintiff class. The Government, as intervenor, sought to recover for medical bills it paid on behalf of Medicare beneficiaries who received treatment related to silicone breast implants. The district court dismissed the Government's complaint in intervention for failure to state a claim. We conclude that the dismissal was in error. We therefore reverse and remand.

I. BACKGROUND

A. Historical Background

The underlying case is result of an order by the Judicial Panel [**2] on Multi-District Litigation, which

* Honorable Richard D. Cudahy, United States Circuit Judge for the Seventh Circuit, sitting by designation.

consolidated all then-pending products liability claims against the manufacturers of silicone breast implants into a single action before the United States District Court for the Northern District of Alabama. The exact details of the underlying claims are not of significance to the disposition of the appeal before us. It is enough to observe that, in general, the plaintiffs allege that they suffered, or fear that they will contract, a variety of systemic illnesses traceable to silicone breast implants, necessitating in some instances that the implants be surgically removed at considerable expense.

The litigation resulted in a settlement valued at $ 4.2 billion that initially involved eight defendant manufacturers (the "Lindsey settlement"). On September 1, 1994, after conducting a fairness hearing, the district court approved the terms of the Lindsey settlement, with modifications. *See Lindsey v. Dow Corning Corp. (In re Silicone Gel Breast Implant Prods. Liab. Litig.)*, 1994 U.S. Dist. LEXIS 12521, No. CV 92-P-10000-S, MDL No. 926, Civ. A. No. CV94-P-11558-S, 1994 WL 578353 (N.D. Ala. Sept. 1, 1994) (approving modified settlement and redefining parameters of class membership). Subsequently, one [**3] of the larger defendants, Dow Corning, declared bankruptcy, and several other defendants (apparently dissatisfied with the court-imposed modifications) chose not to participate in the settlement, leaving the following companies as appellees now before us: Baxter International, Inc.; Bristol-Myers Squibb Co., Minnesota Mining and Manufacturing [*873] Co. ("3M"); Union Carbide Corp.; and Union Carbide Chemical & Plastics Co.

After the modifications were publicized to class members, and after the settlement was restructured to take account of Dow Corning's bankruptcy filing, the district court gave final approval to the settlement by order of December 22, 1995. This became known as the "Revised Settlement Program," or RSP. The participating implant manufacturers are referred to collectively as "the RSP Defendants," [1] the appellees before us.

[**4] The revised settlement class covered personal injury or death claims by members of a class consisting of: persons who received silicone breast implants before June 1, 1993; all children born to mothers with breast implants before April 1, 1994; and their spouses or other relatives. The Government, [2] as well as a number of private insurers, moved to intervene prior to approval of the settlement for purposes of asserting claims for reimbursement of medical claims paid on behalf of class members. The district court denied these motions as premature. Its order stated, in pertinent part: "The court will consider these issues at a later time, before any distributions... are made, and hopefully on the basis of motions that in some appropriate manner identify the persons on whose behalf subrogation claimants have paid medical expenses, rather than simply assert a general claim against the class."

[**5] In accordance with the settlement, the RSP Defendants created a Claims Office to review the documentation submitted by prospective class members and determine what level of benefits, if any, applicants were eligible to receive. Also as part of the claims process, the district court appointed an Escrow Agent, who is responsible for overseeing the investment and disbursement of the settlement proceeds. The position has been held since its inception by Edgar C. Gentile, III. The district court granted the Escrow Agent, as an agent of the court, "judicial immunity" for actions taken in his quasi-judicial capacity, unless he acts in the clear absence of jurisdiction.

The settlement resulted in the creation of two funds relevant to this case. The principal fund, called the RSP Settlement Fund (or sometimes MDL 926 Settlement Fund) is the account from which claims are paid. The second, the Common Benefit Fund, was created by a surcharge on the RSP Defendants for purposes of paying legal fees and expenses incurred for the "common benefit" of all claimants. Both funds are administered by the Escrow Agent.

The RSP Defendants made their first payment into the settlement fund in January of [**6] 1996, and at the direction of the district court, the Escrow Agent began issuing settlement payments to class members in mid-1996. According to the Government's Complaint, about 81,000 claimants [*874] had received some payment from the RSP as of April 1999. To date, more than 400,000 women have registered as potential

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[1] The settlement agreement purported to make the class claimants, rather than the RSP Defendants, liable for reimbursement claims by the Government or by other insurers. The district court did not, however, render its decision based on any agreement by the parties that the RSP Defendants were not liable. Wisely, none of the defendants attempts to argue here that parties could override a statutory right of action afforded to the Government by a contractual arrangement to which the Government was not a party.

[2] When this case was initiated, the agency administering the Medicare program was known as the Health Care Financing Administration (HCFA), a subunit of the Department of Health and Human Services (HHS). Subsequently, the unit was renamed as the Centers for Medicare and Medicaid Services (CMS). For simplicity, we refer to the intervenor/appellant here as "HHS," "the Government" or "Medicare."

claimants, and the RSP Defendants have paid more than $ 1 billion into the RSP Settlement Fund. More than 52,000 breast implant recipients opted out of the settlement class, according to the Complaint, and the Defendants have made payments outside the RSP process to an unspecified number of them.

It is not clear from the record to what extent the RSP Defendants carried liability insurance coverage (other than "self insurance," about which more will be said shortly) for the events giving rise to the class members' claims, or to what extent these defendants have received compensation from such insurance for payments made into the two settlement funds. It is apparent that the implant companies had at least some liability coverage, because the settlement agreement expressly provides for the Defendants' insurers to have access to the otherwise confidential records of class claimants. [**7] We therefore take as established for purposes of this appeal that some third-party insurance coverage exists.

Beginning in 1995 and continuing through March of 2000, the Government entered into a series of "tolling agreements" with the RSP Defendants while negotiating over the Government's access to information about the settlement participants, for purposes of determining which class members may have received Government health benefits for which the Government was entitled to reimbursement. Under these tolling agreements, the Defendants agreed that they would not argue laches, statute of limitations or similar "timeliness" defenses if the Government was forced to file suit. In exchange, the Government agreed to forego filing suit during settlement negotiations. Negotiations between the Government and the RSP Defendants did not produce an agreement. Consequently, in March of 2000, the Government filed the complaint in intervention giving rise to this appeal.

B. The Medicare Secondary Payer (MSP) Statute

The Government's Complaint initially relied on two distinct but related statutes and their accompanying regulations: (1) the Medicare Secondary Payer ("MSP") statute, *42 U.S.C. § 1395y(b)* [**8] , and (2) the Medical Care Recovery Act ("MCRA"), *42 U.S.C. § 2651*. Although all of the Government's claims were dismissed, it is appealing only the dismissal of the MSP claim. [3]

The MSP is actually a collection of statutory provisions codified during the 1980s with the intention of reducing federal health care costs. See *Zinman v. Shalala*, 67 F.3d 841, 845 (9th Cir. 1995) [**9] ("The transformation of Medicare from the primary payer to the secondary payer with a right of reimbursement reflects the overarching statutory purpose of reducing Medicare costs."); *Provident Life & Accident Ins. Co. v. United States*, 740 F. Supp. 492, 498 (E.D. Tenn. 1990) ("The intent of Congress in shifting the burden of primary coverage from Medicare to private insurance carriers was to place the burden [*875] where it could best be absorbed."). *HN1* In a nutshell, the MSP declares that, under certain conditions, Medicare will be the secondary rather than primary payer for its insureds. Consequently, Medicare is empowered to recoup from the rightful primary payer (or from the recipient of such payment) if Medicare pays for a service that was, or should have been, covered by the primary insurer. Although the statute is structurally complex - a complexity that has produced considerable confusion among courts attempting to construe it - the MSP's function is straightforward. As we explained in *Cochran v. United States Health Care Fin. Admin.*, 291 F.3d 775, 777 (11th Cir. 2002):

> If payment for covered services has been or is reasonably expected to be made by someone else, Medicare does not [**10] have to pay. In order to accommodate its beneficiaries, however, Medicare does make conditional payments for covered services, even when another source may be obligated to pay, if that other source is not expected to pay promptly.

Medicare originated as a series of amendments to the *Social Security Act* enacted in 1965, providing a source of payment for hospital care for those over 65. The program was, for the most part, the primary source of payment for its beneficiaries even when another source of coverage existed. However, the 1965 amendments also provided that coverage would be secondary to workers' compensation benefits, and that any payment to or on behalf of a Medicare beneficiary eligible for workers' compensation benefits would be contingent upon reimbursement. See S. Rep. No. 404 at § 1862, 89th Cong., 1st Sess. (1965), *reprinted at* 1965 U.S.C.C.A.N. 1965, 2127-28 ("no payment may be made... for any item or service for which payment has been made, or can reasonably be expected to be made, under a workman's compensation law or plan of the United States or a State. Any payment ... with respect to any [such] item or

[3] While the MSP statute is directed at recovery from "primary plans," the MCRA statute is directed at recovery from tortfeasors. It provides that, where the Government is obliged to pay for the medical care of a person who is injured "under circumstances creating tort liability upon some third person... to pay damages therefor," the Government has the right to recover from the tortfeasor (or their insurers) the "reasonable value" of the care it provides. 42 U.S.C. § 2651(a); see United States v. Haynes, 445 F.2d 907, 908-09 (5th Cir. 1971) (discussing history and purpose of MCRA statute).

service must be conditioned on reimbursement [**11] being made to the appropriate trust fund for such payment if any when notice or other information is received that payment for such item or service has been made under such a law or plan."); see also *Parkview Hosp., Inc v. Roese*, 750 N.E.2d 384, 388 (Ind. Ct. App. 2001) (discussing early history and evolution of MSP statute). That language became the template for the modern MSP provision.

> In pertinent part, the MSP statute in its current form provides:
>
> *HN2* (A) In general
>
> Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that -
>
> ...(ii) payment has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations) under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance.
>
> In this subsection, the term "primary plan" means... a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) [**12] applies. [4] [*876]
>
> (B) Repayment required
>
> (i) Primary plans
>
> Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information is received that payment for such item or service has been or could be made under such paragraph.
>
> (ii) Action by United [**13] States
>
> In order to recover payment under this subchapter for such an item or service, the United States may bring an action against any entity which is required or responsible under this subsection to pay with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity), or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need for the item or service.
>
> (iii) Subrogation rights
>
> The United States shall be subrogated (to the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

42 U.S.C. § 1395y(b)(2)(A)-(B). *HN4* *Subparagraph (b)(3)(A)*, which is referenced above, provides for a private right of action, with double damages available, if a primary plan "fails to provide for primary payment (or appropriate reimbursement) [**14] in accordance with" the preceding MSP regulations. See *42 U.S.C. § 1395y(b)(3)(A)*.

Pursuant to these provisions of the MSP statute, HHS has enacted regulations setting forth the means by which the Government can bring an action to recoup payments from a primary coverage plan. These regulations read, in pertinent part:

> *HN5* If a Medicare conditional payment is made, the following rules apply:
>
> (a) *Release of information.* The filing of a Medicare claim by or on behalf of the beneficiary constitutes an express authorization for any entity, including State Medicaid and workers' compensation agencies, and data depositories, that possess information pertinent to the Medicare claim to release that information to CMS. This information will be used only for Medicare

[4] Part of the dispute in this case revolves around the meaning and scope of the statutory term "self-insured plan." Two HHS regulations are pertinent. *HN3* Under 42 C.F.R. § 411.50(b), a "self-insured" plan "means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier." Under 42 C.F.R. § 411.21, a "plan" is defined as "any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness."

claims processing and for coordination of benefit purposes.

(b) *Right to initiate recovery.* CMS may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan...

...(e) *Recovery from third parties.* CMS has a direct right of action to recover from any entity [**15] responsible for making primary payment. This includes an employer, an insurance carrier, plan, or program, and a third party administrator... [*877]

...(g) Recovery from parties that receive third party payments. CMS has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, state agency, or private insurer that received a third party payment.

(h) Reimbursement to Medicare. If the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 60 days.

(i) Special rules. (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed as required by paragraph (h) of this section, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

42 C.F.R. § 411.24. Additionally, *HN6* the regulations define "prompt" or "promptly," when used in connection with third-party payments, to mean "payment within 120 days after receipt of the claim." 42 C.F.R. § 411.21 [**16]

The MSP, in its present form, originated with enactment of the Omnibus Budget Reconciliation Act ("OBRA") of 1980, Pub.L. No. 96-499, § 953, 94 Stat. 2599 (1980). *HN7* OBRA amended the *Medicare Act* to provide that Medicare payments "may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made (as determined in accordance with regulations) ... under an automobile or liability insurance policy ... or under no fault insurance." [5]

Since enacting the MSP statute, Congress has expanded its reach several times, making Medicare secondary to a greater array of primary coverage sources, and creating a larger spectrum of beneficiaries who [**17] no longer may look to Medicare as their primary source of coverage. [6] More significantly for our purposes, Congress has repeatedly clarified and augmented the Government's powers to recoup conditional Medicare payments from primary sources.

[**18] *HN8* The Deficit Reduction Act ("DERFA") of 1984 conferred on the Government a direct right of action to recover its payments from any entity "which would be responsible for payment" under a "law, policy, plan or insurance," and provided that the Government would be subrogated to the right of any individual or entity to receive payment. DERFA also modified the original wording of the secondary payment provision by adding the modifier "promptly," so that the pivotal phrase dictated [*878] that a Medicare payment "may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made promptly ... with respect to such item or service, under a workman's compensation plan or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or no-fault insurance(.)" H. Res. 4170, 98th Cong., 2d Sess., 98 Stat. 494 (1984) at § 2344. In OBRA 1986, Congress added the private right of action for double damages codified at 42 U.S.C. § 1395y(b)(3)(A). It also added the cross-reference to that section in § 1395y(b)(2)(B)(ii), which enables the Government [**19] to collect double damages "in accordance with" the new private right of action. H. Res. 5300, 99th Cong., 2d Sess., 100 Stat. 1874 (1986) at § 9319.

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[5] As the measure was originally proposed in the House, Medicare would have been secondary only to automobile insurance; a Senate amendment, adopted in conference, added no-fault and liability insurance. See House Confc. Rep. No. 96-14, 96th Cong., 2d Sess. 133, *reprinted in* 1980 U.S.C.C.A.N. 5903, 5924.

[6] In the Omnibus Budget Reconciliation Act of 1981, Congress augmented the MSP to provide that Medicare would be secondary to group health coverage for end-stage renal patients. H. Res. 3982, 97th Cong., 1st Sess., 95 Stat. 357 (1981) at § 2146. In the Tax Equity and Fiscal Responsibility Act ("TERFA") of 1982, Congress made Medicare the secondary payer for "working aged" employees and their spouses between the ages of 65 and 69 belonging to large employer group health plans (covering twenty or more workers). H. Res. 4961, 97th Cong., 2d Sess., 96 Stat. 324 (1982) at § 116. In the Omnibus Budget Reconciliation Act ("OBRA") of 1986, Congress made Medicare the secondary payer for disabled individuals enrolled in large employer group health plans. H. Res. 5300, 99th Cong., 2d Sess., 100 Stat. 1874 (1986) at § 9319.

II. THE DECISION BELOW

The Government's Complaint advanced nine counts: (1) a claim for reimbursement against the RSP Defendants as third-party payers under the MSP; (2) double damages against the RSP Defendants as third-party payers under the MSP; (3) single damages under the MSP against the RSP Defendants as entities that caused payments to be made, or received such payments, from product liability insurers; (4) a subrogation claim under the MSP against disbursements from the MDL Settlement Fund and/or the Common Benefit Fund; (5) a claim for declaratory relief that the RSP Defendants are liable under the MSP to reimburse Medicare for past payments to breast implant patients, and are obligated under 42 C.F.R. § 411.25 to provide Medicare with notice of all payments to Medicare beneficiaries; (6) a single damages claim under the MSP against the Escrow Agent as a person who received payment from the RSP Defendants and/or from product liability insurers to pay the claimants; (7) a claim for injunctive relief [**20] under the MSP to enjoin the Escrow Agent from making disbursements to Medicare patients pending resolution of Medicare's MSP claims and to compel disclosure of identifying information concerning all past or contemplated settlement payments to Medicare beneficiaries; (8) a claim for injunctive relief similar to Count VII under the MCRA, and (9) a demand under the MCRA for payment from the MDL Settlement Fund of the Government's reasonable costs for paying for care of Medicare patients for injuries alleged to be caused by a breast implant. Thus, Counts I through VII arose under the MSP or its regulations, while counts VIII and IX arose under the MCRA. [7]

The district court (after first granting the Plaintiffs' Steering Committee the right to intervene) granted the motions to dismiss filed by the RSP Defendants, the Escrow Agent, and the Plaintiffs' Steering Committee, finding that the Government had failed to state a claim upon which relief [**21] could be granted. [8]

The court first evaluated whether the Government had a claim for reimbursement under 42 U.S.C. § 1395y(b), the MSP statute. The court found that - whether the Government was bringing a direct action in its own right under the statute or was acting as the subrogee to the patient's rights - an essential element to state a claim under the MSP was to identify both the services provided and the patient who received them. In addition to the need for the Defendants to know the identity of the [*879] patients and the amount in dispute, the court noted that the beneficiaries themselves are interested parties and have the right to challenge the reimbursement request and to petition the Government to waive its claim.

The court rejected the Government's argument that it was unable to plead the identity of the beneficiaries in [**22] question because of the settlement's confidentiality provisions. The court found that the Defendants were under no statutory duty to collect information about the identity of potential claimants, and that absent such a duty, it was irrelevant whether the settlement was structured with the purpose of evading disclosure. Because the Government had an alternative means of relief - like any other insurer, it could file a petition for reimbursement with the RSP Claims Office - the court found no need to relieve the Government from compliance with the MSP statute or the pleading standards of Fed. R. Civ. P. 8(a).

Next, the court considered whether the Government was entitled to reimbursement under 42 C.F.R. § 411.24(i), the "double payment" regulation adopted pursuant to the MSP. Under Section 411.24(i), a "third party payer" may be required to reimburse Medicare if it paid a provider or a claimant when it knew, or should have known, that Medicare had made a conditional primary payment as provided by the MSP. The district court found this regulation inapplicable, because the relevant portion of the MSP statute applies only to insurers or "self-insured plans." The [**23] court rejected the Government's contention that the implant manufacturers could be viewed as "self-insured plans." The RSP Defendants were thus outside the coverage of the statute and not subject to the "double payment" regulation.

Further, the court found that the Government had no direct right of action against a third-party payer that had already made payment to its insured, because such a payer was no longer "required or responsible... to pay" as provided by the MSP statute, § 1395y(b)(2)(B)(ii). The Government may proceed against such an insurer only in its role as subrogee, the court held. Relying on Health Ins. Ass'n of America v. Shalala, 306 U.S. App. D.C. 104, 23 F.3d 412 (D.C. Cir. 1994) ("HIAA"), and on general principles of common law, the court held that, as a subrogee, the Government was required to "plead and prove [that] the third-party payer knew or should have known of Medicare's conditional payments at the time payment was made to the beneficiary." Because, in the district court's view, the Government failed to do so,

[7] As noted above, the Government has now abandoned its MCRA claims.

[8] The opinion below was published as In re Silicone Gel Breast Implants Products Liability Litig., 174 F. Supp. 2d 1242 (N.D. Ala. 2001).

its claims under the "double payment" provision were fatally flawed.

The court declined to adopt the Government's interpretation [**24] that the existence of the MSP statute itself puts insurers on constructive notice that they must inquire into whether Medicare has paid a beneficiary before they pay a claim. Rather, citing HIAA, the court held that "knowledge" requires the Government to show that, at the time it paid the claim, the insurer had "direct information... or information necessary to draw the conclusion" that Medicare had made a conditional payment to the particular recipient. It was insufficient, the court held, that the Government's prior intervention in the case *generally* alerted the Defendants that Medicare might have paid some claims.

The court rejected the Government's contention that the Defendants' knowledge was a factual matter to be proven at trial. The court observed that the Government's own complaint alleged that the RSP Defendants "did not ascertain" whether Medicare had made payments on behalf of any of the RSP claimants. With that assertion, [*880] the court felt that the Government had effectively pled itself out of court.

Next, the court addressed whether the Government could bring a claim in Count II against the RSP Defendants for double damages pursuant to *42 U.S.C. § 1395y(a)(3)* [**25] and *42 C.F.R. § 411.24(c)(2)*. Having held that the Defendants were not liable even for single damages, the district court summarily rejected the Government's claim for double damages.

Similarly, the district court summarily rejected the Government's claims for declaratory relief (Count V) and injunctive relief (Count VII). The court then considered whether any of the defendants could be liable under the MSP as entities that "received payment," as provided in *42 U.S.C. § 1395y(b)(2)(B)(ii)*. (Although the court acknowledged that the Government's claim under this section ran against both the RSP Defendants and the Escrow Agent, its discussion focused almost exclusively on the role of the Escrow Agent.) First, the court - again relying on HIAA - held that a mere "pass-through" could not be said to have "received" payment under any ordinary understanding of that term, since "receipt" suggests a degree of autonomous control. Further, the court observed that the term "recover" in the statute suggested that the Government must proceed against an entity actually in possession of the money - either the ultimate payer or the ultimate [**26] payee - and not an entity that temporarily held the money and relinquished it. Additionally, the court observed that the Defendants did not fit either the statute's or HHS regulations' illustration of who qualifies as an entity that receives payment: the statute uses the illustration "any physician or provider," while *42 C.F.R. § 411.24(g)* refers to "a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment." All of those entities, the court observed, are likely to be ultimate recipients of payment rather than mere conduits. Where an entity has merely remitted payment as a pass-through, the court held, that entity is reachable only through *42 C.F.R. §§ 411.24(i)*, which requires proof of knowledge of Medicare's prior payment that is lacking in this case.

III. DISCUSSION

HN9 We review a district court's grant of a motion to dismiss for failure to state a claim *de novo*. *Abate of Georgia, Inc. v. Georgia*, 264 F.3d 1315, 1315 (11th Cir. 2001). *HN10* A motion to dismiss a complaint in intervention is reviewed under the same standard applicable to consideration [**27] of a motion to dismiss the original plaintiffs' complaint. *Southwest Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 819-20 (9th Cir. 2001). *HN11* In evaluating the sufficiency of a complaint under *Rule 12(b)(6)*, courts must be mindful that the Federal Rules require only that the complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief(.)" *Fed. R. Civ. P. 8(a)*. *HN12* In applying *Rule 12(b)(6)*, "a complaint should not be dismissed for failure to state a claim unless it appears beyond a doubt that the [complainant] can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S. Ct. 99, 102, 2 L. Ed. 2d 80 (1957).

The district court granted the motion on two grounds: first, that the Government's Complaint was defective because it did not include the identity of the recipients of federal health care benefits and the nature of the expenditures, and second, that the MSP statute did not entitle the Government to proceed on its chosen theories against these defendants. Thus, we must [*881] consider both whether the Government has viable claims under the [**28] applicable law, and, if so, whether the Government's pleading was sufficient to invoke the MSP.

A. Sufficiency of Complaint

The district court held that, "at a minimum," a complaint under the MSP statute must identify the Medicare beneficiaries for whose care reimbursement is sought. Because the Complaint here failed to do so, the court held, the MSP counts were subject to dismissal.

HN13 Because the Federal Rules embody the concept of liberalized "notice pleading," a complaint need contain only a statement calculated to "give the defendant fair notice of what the plaintiff's claim is and the grounds

upon which it rests." Conley, 355 U.S. at 47, 78 S. Ct. at 103; see also Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC, 331 U.S. App. D.C. 226, 148 F.3d 1080, 1086 (D.C. Cir. 1998) ("[A] plaintiff need not allege all the facts necessary to prove its claim."). We have observed that *HN14* the threshold of sufficiency to which a complaint is held at the motion-to-dismiss stage is "exceedingly low." See In re Southeast Banking Corp., 69 F.3d 1539, 1551 (11th Cir. 1995) (For better or for worse, the Federal Rules of Civil Procedure do not [**29] permit district courts to impose upon plaintiffs the burden to plead with the greatest specificity they can.").

HN15 Rule 24 requires merely that an intervenor's petition "shall state the grounds [for intervention] and shall be accompanied by a pleading setting forth the claim or defense for which intervention is sought." Fed. R. Civ. P. 24(c). "The determination of whether the proposed intervenor's complaint states a cause of action is controlled by the general rules on testing a pleading; the factual allegations of the complaint are assumed to be true... and the pleading is construed liberally in support of the pleader." Pin v. Texaco, Inc., 793 F.2d 1448, 1450 (5th Cir. 1986) (internal quotes and citation omitted); accord County of Santa Fe v. Public Serv. Co. of N.M., 311 F.3d 1031, 1035 (10th Cir. 2002).

The Supreme Court has said in the context of a standing determination that *HN16* at the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim." Nat'l Org. for Women, Inc. v. Scheidler, 510 U.S. 249, 256, 114 S. Ct. 798, 803, 127 L. Ed. 2d 99 (1994) [**30] (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 561, 112 S. Ct. 2130, 2137, 119 L. Ed. 2d 351 (1992)). In Swierkiewicz v. Sorema, N.A., 534 U.S. 506, 511, 122 S. Ct. 992, 997, 152 L. Ed. 2d 1 (2002), the Court held that in the employment discrimination context, a complaint is not subject to dismissal for failure to state a claim merely because it fails to "plead facts establishing a prima facie case" of discrimination. As the Court emphasized there:

> *HN17* The liberal notice pleading of Rule 8(a) is the starting point of a simplified pleading system. ... Rule 8(a) establishes a pleading standard without regard to whether a claim will succeed on the merits. 'Indeed, it may appear on the face of the pleadings that a recovery is very remote and unlikely but that is not the test.'

Id. at 122 S. Ct. at 999 (quoting Scheuer v. Rhodes, 416 U.S. 232, 236, 94 S. Ct. 1683, 40 L. Ed. 2d 90 (1974)).

HN18 Courts typically allow the pleader an extra modicum of leeway where the information supporting the complainant's case is under the exclusive control of the defendant. See Peters v. Amoco Oil Co., 57 F. Supp. 2d 1268, 1284-85 (M.D. Ala. 1999) [*882] [**31] (holding that complaint setting forth general allegations about nature of conspiracy was sufficient despite heightened pleading standard applicable to conspiracy claims under Fed. R. Civ. P. 9(b), where information about extent of alleged conspiracy was within defendants' exclusive control); see also Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp., 711 F.2d 989, 995 (11th Cir. 1983) (holding that liberalized consideration of complaint espoused in Conley "is particularly true in an antitrust suit where the proof and details of the alleged conspiracy are largely in the hands of the alleged co-conspirators.").

The situation presented here - an intervenor bringing a claim on the basis of injury to a large group of others, the identities of whom the intervenor claims cannot be determined without discovery - is not unlike that commonly presented in a class action, such as the one that underlies our case. *HN19* In a class action, it is sufficient that a complaint generally give the defendant notice of the nature and scope of the plaintiffs' claims; it is not necessary that the class representatives plead evidence or otherwise meet any burden [**32] beyond the minimal Rule 8 standard. See 7B WRIGHT, MILLER & KANE, FEDERAL PRACTICE & PROCEDURE § 1798 (2d ed. 1986) at 417-18 ("All of the pleading provisions of the federal rules are applicable in class actions and operate in much the same fashion as they do in other litigation contexts. ... No greater particularity is necessary in stating a claim for relief in a class action than in other contexts."); Alba Conte & Herbert B. Newberg, 6 NEWBERG ON CLASS ACTIONS § 18:46 (4th ed. 2003) ("It is not necessary... that class members be specifically identified; the plaintiff need not name names. In addition, the complaint need not set forth the exact number of class members. It is sufficient to indicate the approximate size of the class and provide or describe facts making ultimate identification of class members possible when that identification becomes necessary."). Indeed, the Supreme Court's seminal statement of the standard for dismissal, Conley, involved a class action by African-American railroad clerks who alleged that their union had breached its duty of fair representation by discriminating against them.

In view of the foregoing, we find that the district court applied [**33] too exacting a standard when it found the

Government's Complaint fatally deficient for failing to identify each member of the plaintiff class on whose behalf Medicare made a conditional payment. [9] The crucial information that the district court here found necessary to complete the Government's Complaint - "the Medicare beneficiaries who have received benefits from the defendants" - is outside the Government's control. At best, the Government may be [*883] able to generate a list of all patients who received treatment for breast implant-related medical conditions during the period covered by the RSP settlement. [10] Such a list would be wildly over-inclusive, as it could include: patients whose implants were not manufactured by any of the RSP Defendants; patients who had their implants removed for reasons other than tortiously inflicted injury; patients who opted not to participate in the settlement; and patients participating in the class whose application for RSP benefits may (for whatever reason) not be approved by the Claims Office so that they will never receive payment. The Government could not in good faith purport to be bringing its Complaint on behalf of such a patently inaccurate [**34] list of beneficiaries. See *Fed. R. Civ. P. 11(b)* *HN20* ("By presenting to the court... a pleading, written motion, or other paper, an attorney or unrepresented party is certifying that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances... the allegations and other factual contentions have evidentiary support"). While the Government might be able to arrive at a rough approximation, the RSP Defendants (either directly or through the Claims Office) have access to: (1) the names of the approximately 400,000 registered potential claimants, and (2) the approximately 81,000 people whose claims, to date, have been deemed worthy of payment. They are, consequently, in the far more advantageous position to compile an accurate list of Medicare patients for whom MSP payments have been made or requested. [11]

The pleading standards urged by the RSP Defendants are akin to the heightened requirements of *Fed. R. Civ. P. 9*, which apply to claims of fraud, mistake, duress and other "special matters." [**36] *HN21* Where *Rule 9* is implicated, plaintiffs must plead not only the general nature of their injuries but also the specifics of how and when they were injured. See, e.g., *Brooks v. Blue Cross & Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1380-81 (11th Cir. 1997) (under *Rule 9(b)*, plaintiff alleging fraud must plead "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud"); *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-62 (6th Cir. 1993) (*Rule 9(b)* requires plaintiff in fraud case "at a minimum, to allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud"). By implication, then, a complaint governed by the ordinary standard of *Rule 8* - and there is no dispute that *Rule 8* applies here - need not allege the particulars of [*884] each instance [**37] of injury in order to survive a motion to dismiss. [12]

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[9] In determining the required elements of a proper complaint, the district court placed principal reliance on In re Dow Corning Corp., 244 B.R.705 (E.D. Mich. 1999), which involved Government claims under the MSP and MCRA seeking reimbursement from a manufacturer that opted out of this litigation. See id. at 713 (detailing necessary contents of Government's claims). Significantly, Dow Corning arose in the context of a Chapter 11 proceeding to validate the cramdown of a plan of reorganization, pursuant to 11 U.S.C. § 1129(b)(1), not in the context of a Rule 12(b)(6) motion to dismiss. Consideration of a § 1129(b)(1) motion requires the court to review evidence and resolve issues of fact. Thus, the Government did not have the benefit of the deferential review afforded to allegations at the motion-to-dismiss stage. Dow Corning's standard for what constitutes an adequately supported objection to the validation of a § 1129(b)(1) reorganization is of limited usefulness in determining what an ordinary civil complaint in intervention must contain.

[10] Even this is a dubious assumption. Many women will doubtless have received Medicare-compensated treatment for generic symptoms not specifically identified on their providers' bills as related to breast implants, or perhaps not diagnosed as implant-related until later in the course of treatment.

[11] The district court believed that the Government was required to plead the names of Medicare patients who have actually received payment from the Defendants. Because tens of thousands of pending claims remain to be evaluated by the RSP Claims Office, even if the Government were able to produce a perfectly accurate list in compliance with the district court's standards, such list would be obsolete essentially from the day of submission due to the ongoing claims adjudication process. We fail to see how the conduct of this litigation would be aided by forcing Medicare at this initial stage to produce what will necessarily be a grossly inaccurate and constantly changing claimant list.

[12] The Defendants argue that it would be inequitable to allow Medicare to proceed on the basis of an unspecific complaint when the Government failed to request access to the names of the RSP claimants - a request that the district court had indicated it might view favorably. Whether or not the Government conducted itself with optimal diligence is not conclusive. A complaint that

It is significant here that, out of a class of 400,000 potential claimants, it appears beyond dispute that at least some class members will have received conditional Medicare payments. [13] No one suggests to the contrary. Therefore, [**38] given the benefit of discovery, it appears not only possible but in fact inevitable that the Government will turn up a number of claims eligible for reimbursement. That the Government cannot now provide a name, date and dollar amount corresponding to any particular Medicare payment for which reimbursement is owed does not indicate beyond doubt that it has "no case," which is what a court must find to grant a motion to dismiss. [14]

[**39] Finally, we note that requiring the Government to plead with the specificity Defendants seek would run counter to the intent of the MSP statute. In carrying out its principal purpose of shifting the burden of paying for health care from Medicare to private insurers, the MSP creates as a practical matter a need for insurers to determine, before paying a disputed liability claim (involving among its alleged damages medical expenses likely to have been paid by Medicare), whether the Government has made a conditional payment, [*885] upon peril of being forced to pay the same claim twice. As the second payer, such insurer is in a position to determine which claim has been, or is at risk of being, paid twice, while Medicare, as the first payer, is not. Because the statute is built on the recognition that Medicare frequently will not know which of its payments has been subsequently duplicated by an insurer, it would - in this unique setting of a class action involving thousands of claimants - defeat the purpose of the statute to require that the Government identify each patient, procedure, and payment amount at the pleading stage without benefit of discovery.

We readily conclude that the district [**40] court erred in dismissing the complaint for failure to identify the beneficiaries for whose care reimbursement is sought.

B. Scope of MSP Statute

1) Were Medicare's payments conditioned on reimbursement?

The RSP Defendants argue here that the Government's right to recoup its payments never arose, because under the terms of the MSP statute, Medicare's payments were not "conditional" at all. The disputed statutory provisions, *42 U.S.C. §§ 1395y(b)(2)(A) and (b)(2)(B)*, provide:

> *HN22* (A) In general
>
> Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that -
>
> (i) payment has been made, or can reasonably expected to be made, with respect to the item or service as required under [regulations governing group health plans], or
>
> (ii) payment has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations)

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is otherwise satisfactory under Rule 8 - as is this one - does not become inadequate merely because the complainant had access to more detailed information but failed to include it. (We note that the district court did not rely on the Government's failure to move for disclosure of the identity of the RSP claimants as a basis for dismissing the Complaint.)

[13] In a sworn declaration submitted to the district court in May 2000, the Government reported that 457 people (140 who participated in the RSP settlement and 317 who opted out) had identified themselves to HHS as having received payment from the breast implant litigation. This number hints at the immense litigation management problems that would ensue if the Government were forced to plead the individualized medical and payment histories of each of its beneficiaries.

[14] Our facts materially differ from those presented in City of Birmingham v. American Tobacco Co., 10 F. Supp. 2d 1257 (N.D. Ala. 1998), on which the district court relied. In City of Birmingham, which involved a somewhat analogous claim for recovery of health care expenses under a state statute, the district court found that the plaintiffs were required to plead details about each patient and each expenditure for which reimbursement was sought. In that non-class action, however, there was considerable doubt as to whether the plaintiffs could identify even a single person for whose care they were entitled to reimbursement, and information as to the patients' identities and medical history was within the *plaintiffs'* exclusive control. It is also noteworthy that, even in City of Birmingham, the court did not dismiss the complaint outright, but rather, granted the plaintiffs leave to amend.

For similar reasons, we do not find the principal case cited by Defendants, Health Care Serv. Corp. v. Brown & Williamson Tobacco Corp., 208 F.3d 579 (7th Cir. 2000), to be on point. In Brown & Williamson, the Seventh Circuit upheld the dismissal of a subrogatory claim by various Blue Cross/Blue Shield associations suing tobacco companies to recover for smoking-related health care expenses for their insureds. Although the court did find the complaint lacking because it failed to plead the identity of the parties insured, its principal weakness was a failure to show either a right to recovery or a basis for federal jurisdiction, both of which are supplied in our case by the MSP statute. Moreover, as with City of Birmingham, Brown & Williamson did not arise out of an underlying class action, which (in our case) itself serves to give the defendants notice of the universe of patients for whose expenses reimbursement may be sought.

> under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance. ...
>
> In this subsection, the term [**41] "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies.
>
> (B) Repayment required
>
> (i) Primary plans
>
> Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information is received that payment for such item or service has been or could be made under such paragraph.

Defendants argue that *subparagraph (A)* operates as a limitation on the right of reimbursement in *subparagraph (B)*, so that a Medicare payment is conditioned on reimbursement only if "payment has been made or can reasonably be expected to be made promptly" by another insurer. In other words, Defendants argue that Medicare is entitled to reimbursement only if Medicare pays after payment from a primary insurance source either has already been made or is expected promptly. Otherwise, in Defendants' view, Medicare's payment [**42] is unconditional and may not be recouped.

[*886] Grammatically, Defendants' interpretation is a possible reading of the statute. However, we think the much more plausible interpretation of the statute is that *HN23* Medicare would endeavor not to pay where a "primary plan" has paid or is expected to pay promptly, but any payment that Medicare does make is secondary and is subject to reimbursement from sources of primary coverage under the statute. This more plausible interpretation is also a grammatically correct construction of the language of the statute. The crucial phrase in *§ 1395y(b)(2)(B)(i)* - "to which *subparagraph (A)* applies" - plausibly modifies "any item or service," meaning any item or service covered by a primary plan as defined in the last paragraph of *§ 1395y(b)(2)(A)*. The court in *Brown v. Thompson*, 252 F. Supp. 2d 312, 317 (E.D. Va. 2003) recently rejected Defendants' interpretation, and adopted the interpretation we adopt today. The Brown court held:

> The reference in *subparagraph B* to 'item or service to which *subparagraph A* applies' must refer only to that portion of *subparagraph A* that defines a primary plan. In other words, the reference to *subparagraph A* [**43] in *subparagraph B* serves simply to define the universe of reimbursable payments to consist of those where primary coverage exists. ... Properly construed, therefore, *subparagraph B* requires reimbursement for a payment, as here, that 'has been made' from a 'primary plan' as defined in *subparagraph A*.

It is clear that an item or service paid by a primary plan defined in the last paragraph of *subparagraph (A)* is, in the language of *subparagraph (B)*, an "item or service to which *subparagraph (A)* applies." In other words, *subparagraph (A)* applies by defining the universe of reimbursable payments.

Our interpretation is further supported by a close examination of the language of *subparagraphs (A)* and *(B)*. *Subparagraph (B)* refers to payments "with respect to any item or service to which *subparagraph (A)* applies." This would include any payments contemplated by *subparagraph (A)*. Turning to *subparagraph (A)* to ascertain what payments it contemplates, we see that it contemplates that Medicare should not pay if payment has been made or is reasonably expected from a group health plan (*subparagraph (A)(i)*), and that Medicare should not pay if payment has been made or can reasonably [**44] be expected to be made promptly under plans including liability insurance or self-insured plans (*subparagraph (A)(ii)*). By contrast *subparagraph (A)* clearly contemplates Medicare will pay when it does not reasonably expect prompt payment by such primary obligors - precisely the payments which Defendants argue are not reimbursable. We believe that the much more plausible interpretation of the statutory language indicates that these payments are reimbursable. These are payments "with respect to any item or service to which *subparagraph (A)* applies" because *subparagraph (A)* defines their universe and contemplates Medicare paying them.

Although only our more plausible interpretation comports with the purpose of the statute, see infra, the two grammatically correct potential interpretations mean that the statute might be considered ambiguous. *HN24* Where such ambiguity exists, the reasonable interpretation

of the agency charged with implementing the statute is entitled to judicial deference, under the principles enumerated by the Supreme Court in Chevron USA, Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984).

HN25 The first [**45] step in the two-step Chevron review is to determine whether Congress [*887] has "directly and unambiguously spoken to the precise question at issue." Georgia, Dep't of Medical Assistance ex rel. Toal v. Shalala, 8 F.3d 1565, 1567 (11th Cir. 1993) ("Georgia DMA") (quoting Chevron, 467 U.S. at 842-43, 104 S. Ct. at 2781-82). If so, the court's inquiry is at an end, for it must honor Congress' clearly expressed intent. Determining whether Congress has unmistakably addressed the issue requires looking at "the particular statutory language at issue, as well as the language and design of the statute as a whole." Georgia DMA, 8 F.3d at 1567 (citing Sullivan v. Everhart, 494 U.S. 83, 89, 110 S. Ct. 960, 964, 108 L. Ed. 2d 72 (1990)).

If Congress has not directly addressed the issue, or the statutory provision is ambiguous, we come to the second stage of Chevron: whether the agency's construction of the statute is reasonable and consistent with congressional intent. If so, we must accede to it. See Dawson v. Scott, 50 F.3d 884, 887 (11th Cir. 1994) ("Agency interpretation is reasonable and controlling unless it is 'arbitrary, [**46] capricious, or manifestly contrary to the statute.'") (quoting Chevron, 467 U.S. at 844, 104 S. Ct. at 2782); Bigby v. INS, 21 F.3d 1059, 1063 (11th Cir. 1991) (We defer to an agency's reasonable interpretation of a statute it is charged with administering."). The consistency of an agency's interpretation over time is a factor in determining the level of deference due. Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417, 113 S. Ct. 2151, 2161, 124 L. Ed. 2d 368 (1993); see also Teamsters v. Daniel, 439 U.S. 551, 566 n. 20, 99 S. Ct. 790, 800 n. 20, 58 L. Ed. 2d 808 (1979) ("It is commonplace in our jurisprudence that an administrative agency's consistent, longstanding interpretation of the statute under which it operates is entitled to considerable weight.").

Here, we find that HHS - which was expressly delegated by Congress to formulate rules implementing the MSP statute - has consistently taken the position that Medicare payments are conditional and subject to recoupment regardless of whether another insurer can be expected to render a prompt primary payment. We start with the agency's notion of what it means for [**47] a Medicare payment to be "secondary." HHS regulations state that *HN26* secondary', when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other insurance that is primary to Medicare." 42 C.F.R. § 411.21. In other words, the regulation rejects Defendants' interpretation, and embraces our interpretation - that conditional medical payments are made to beneficiaries whose primary coverage has not yet paid and is not expected to pay promptly.

In updating its regulations to account for congressional revisions in 1984 through 1987, the agency stated its understanding that "Medicare makes conditional primary payment only if the other insurer will not pay promptly." Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 53 Fed. Reg. 22335, 22336 (proposed June 15, 1988). Similarly, in characterizing Congress' 1987 revisions to the secondary payment provisions regarding coverage for end-stage renal patients, HHS stated: "Medicare may not make conditional primary payments on behalf of an ESRD beneficiary who is covered [**48] by an employer group health plan if the plan can reasonably be expected' to pay." Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41717 (Oct. 11, 1989); see alsoMedicare Program, Services Covered Under Automobile Medical, No-Fault, or Liability Insurance; Services Furnished to ESRD Beneficiaries Who Are Covered Under Employer Group Health Insurance, [*888] 48 Fed. Reg. 14802, 14807 (April 5, 1983) ("Congress clearly intended that Medicare not pay first when there is a reasonable expectation that the employer plan will pay as promptly as Medicare. ... Medicare will be primary payer for items and services not covered by the employer plan and will make conditional primary payments if the intermediary or carrier determines that the employer plan will not pay promptly."). These and other authoritative HHS interpretations evidence that the agency has always understood that it will endeavor not to make payments where a payment has already been made by, or can reasonably be expected to be made by, a primary insurer, but that payment may be made conditionally under § 1395y(b)(2)(B) when Medicare does not reasonably expect [**49] prompt primary coverage payment.

We find the agency's interpretation to be in accord with the structure, history and purpose of the MSP statute, all of which plainly indicate that Congress wanted Medicare's payments to be secondary and subject to recoupment in all situations where one of the statutorily enumerated sources of primary coverage could pay instead. It is readily apparent that the interpretation evidenced in the HHS regulations, which we also adopt, correctly implements the statutory purpose. The RSP Defendants do not deny that the clear statutory purpose

of the Medicare Secondary Payer statute was to make Medicare's obligation secondary to that of designated primary obligors, with the intention of reducing federal health care costs. This statutory purpose is universally accepted. It is also clear that HHS' interpretation would fulfill the congressional purpose, while Defendants' interpretation would frustrate that purpose. [15]

[**50] Next we turn from the foregoing general purpose of the statute to the specific language which Defendants argue supports their interpretation: "Any payment under this subchapter with respect to any item or service to which *subparagraph (A)* applies shall be conditioned on reimbursement ...." *§ 1395y(b)(2)(B)(i)*. Defendants argue that *subparagraph (A)* refers to situations where the primary obligor has already paid or can be expected to pay promptly; thus, Defendants argue that Medicare payments are conditional only in such situations. However, *subparagraph (A)* makes is clear that those are the very situations in which Medicare should endeavor not to pay. Thus, Defendants' interpretation would require us to indulge the illogical premise that Congress intended for Medicare to pay claims that it knew for a fact had already been paid, or were about to be paid, by the primary obligor - the very claims which the statute clearly contemplates that Medicare would endeavor not to pay.

Thus, both the general statutory purpose, and the purpose evident in the very language upon which Defendants rely, is manifestly inconsistent with Defendants' interpretation. By contrast, our interpretation, [**51] and that adopted by the regulations, fully implements the general congressional purpose, and is consistent with both the purpose and the precise language of *§§ 1395y(b)(2)(A) and (B)*. In our view, Congress intended that Medicare would *always* be secondary to the sources of [*889] primary coverage enumerated in the statute.

Our interpretation not only fulfills the statutory purpose, but is consistent with the congressional intent as evidenced in the legislative history. Congress quite clearly expressed its understanding of how the secondary payment mechanism was designed to work in 1984, when enacting amendments that clarified the government's direct and subrogatory rights against third-party payors

> The bill establishes the statutory right of medicare [sic] to recover directly from a liable third party, if the beneficiary himself does not do so, and to pay a beneficiary, or on the beneficiary's behalf pending recovery where such third party is not expected to pay promptly.

H.R. Rep. No. 98-432, at 1803 (1984), *reprinted in* 1984 U.S.C.C.A.N. 697, 1417 (emphasis added). Unmistakably, Congress intended that contingent payments made because the primary payer was not [**52] expected to pay promptly would be subject to recovery.

The legislative history of the MSP indicates that it originated as a device to recoup payments from automobile insurance coverage. *See Mason v. American Tobacco Co.*, 212 F. Supp. 2d 88, 93 (E.D.N.Y. 2002) (quoting original House bill, which referred only to "automobile insurance"). It is not at all uncommon for automobile insurance claims to be litigated and thus to take more than 120 days to be resolved. See, e.g., *Waters v. Farmers Texas County Mut. Ins. Co.*, 9 F.3d 397 (5th Cir. 1993) (denying summary judgment on MSP claim arising out of automobile accident three years earlier and remanding case for trial). The same is true of workers' compensation claims, which have been included within the scope of the MSP since its inception. Indeed, Medicare regulations specifically contemplate recovery where the third-party payment is the result of a judgment or a litigation settlement, which as a practical matter will almost always take more than 120 days. *See 42 C.F.R. § 411.37* (providing that Medicare will deduct from its recovery a pro rata share of attorney fees and [**53] other "procurement expenses" incurred to secure a judgment or settlement). Congress fully contemplated such delays when it provided for Medicare to pay contingently. See H.R. Rep. No. 1167, 96th Con., 2d Sess., at 389 (1980) ("Medicare will ordinarily pay for the beneficiary's care in the usual manner and then seek reimbursement from the private insurance carrier after, and to the extent that, such carrier's liability under the private policy for the services has been determined."). If the Defendants' interpretation were correct, it could well preclude recovery from automobile liability or workers' compensation insurance - the very sources for which the MSP was designed - since those sources routinely pay

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[15] If Medicare's payments were conditional only if Medicare paid when the primary obligor had already paid or was expected to pay promptly, as Defendants would have us hold, then the vast majority of Medicare payments for services also covered by primary obligors would not be conditional. This is so because the only payments Defendants want to label as conditional are the very payments which § 1395y(b)(2)(A) provides Medicare should not make at all. Thus, Congress' cost-saving measures would have borne little or no fruit.

claims more than 120 days after the provision of medical treatment.

The historical evolution of these statutory provisions also supports the interpretation adopted by the agency. When Congress expanded the secondary payer provision in the *Omnibus Budget Reconciliation Act of 1981* so that it would include those enrolled in federal employee health plans and end-stage renal patients covered by group health plans, the provision read as follows:

> (2)(A) In the case of an individual [**54] who is entitled to benefits under [Medicare] part A or is eligible to enroll under part B ... payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service furnished during the period described in subparagraph (C) to the extent that payment with respect to expenses for such item or service (i) has [*890] been made under any group health plan ... or (ii) the Secretary determines will be made under such a plan as promptly as would otherwise be the case if payment were made by the Secretary under this title.
>
> "(B) Any payment under this title **with respect to any item or service to an individual described in subparagraph (A)** during the period described in subparagraph (C) shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when notice or other information is received that payment for such item or service has been made under a plan described in subparagraph (A),

See H. Res. 3982, 97th Cong., 1st Sess., 95 Stat. 357 (1981) (emphasis added). Thus, in the 1981 version, it is clear that *subparagraph (B)* incorporates *subparagraph (A)* only to indicate that the two subparagraphs apply [**55] to the same set of individuals - those entitled to benefits under Medicare Part A or eligible to enroll in Medicare Part B - not to the same set of payments.

In the Tax Equity and Fiscal Responsibility Act of 1982 (TERFA), Congress revised the MSP provision so as to make Medicare the secondary payer for "working aged" recipients under age 70 and their spouses enrolled in employer group health plans. TERFA added the following conditional payment provision to

42 U.S.C. § 1395y:

> *HN27* (3)(A)(i) Payment under this title may not be made, except as provided in clause (ii), with respect to any item or service furnished ... to an individual who is over 64 but under 70 years of age ... who is employed at the time such item or service is furnished to the extent that payment with respect to expenses for such item or service has been made, or can reasonably be expected to be made, under a group health plan ...
> (ii) Any payment under this title with respect to any item or service ... shall be conditioned on reimbursement to the appropriate Trust Fund ... when notice or other information is received that payment for such item or service has been made under a [**56] group health plan.

H. Res. 4961, 97th Cong., 2nd Sess., 96 Stat. 324 (1982) (emphasis added). The conditional payment provision, in this iteration, patently applied to any item or service for which a group health plan might pay. It in no way limited the Government's right of recovery to those items or services for which a third-party payment was made or reasonably anticipated before Medicare made its payment.

Congress again amended the MSP in 1986 with the purpose, *inter alia*, of prohibiting employer group health plans from offering lesser benefits to senior citizens based on their Medicare eligibility. At that point, the "secondary payer" provision read:

> (4)(A)(i) A large group health plan may not take into account that an active individual is eligible for or receives benefits under this title ...
>
> "(ii) Payment may not be made under this title, except as provided in clause (iii), with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under clause (i).
>
> "(iii) Any payment under this title **with respect to any item or service to which clause (i) applies** [**57] shall be conditioned on reimbursement to the appropriate Trust Fund established by this title.

See H. Res. 5300, 99th Cong., 2nd Sess., 100 Stat. 1974 (1986). In this incarnation, Medicare's right of reimbursement in subparagraph (A)(iii)

(what is now *subparagraph* [*891] (B)) refers back to and incorporates *subparagraph (A)(i)*, which concerns the duty of large group health plans to render primary payment. Again, this version makes clear that the reference to *subparagraph (A)* in Medicare's right of reimbursement merely characterizes the broad category of coverage to which Medicare will be secondary. It cannot possibly be read as limiting Medicare's right of recovery to payments made after a group health plan has already paid or is expected to pay.

The current wording of the MSP was adopted as part of the Omnibus Budget Reconciliation Act of 1989, H. Res. 3299, 101st Cong., 1st Sess., 103 Stat. 2186 (1989). There is no indication in the legislative history that, between 1986 and 1989, Congress changed its mind and decided that Medicare should cease being the secondary payer for a substantial subset of claims. [16] Although the 1989 amendments obscured the clarity of the prior [**58] versions of the conditional payment provision, we cannot glean from this obscurity an unambiguous legislative purpose to narrow the MSP in the way that Defendants urge.

[**59] Our view is further sharpened by Congress' addition of the modifier "promptly" in 1984. Defendants have offered no logical explanation, and we can discern none, for why Congress would have intended to divest Medicare of the right to pursue recovery if payment from another insurer was probable, yet - because of a coverage dispute - unlikely to occur within the 120-day window of "promptness." [17] Rather, it is apparent that the concern for "promptness" is motivated by a desire to prevent either the health care provider or the patient from going without compensation for a prolonged period while an insurance dispute is being resolved. Indeed, that is exactly how Congress - in enacting an earlier [*892] iteration of the MSP - explained its insertion of the term "promptly" in determining when Medicare may pay conditionally. See H.R.Rep. No. 208, 97th Cong., 1st Sess. 955, 956 (1981), *reprinted in* 1981 U.S.C.C.A.N. 396, 1318 ("The payment arrangements contemplated by the conferees are intended to minimize patient anxiety about the source of payment and to avoid delays in reimbursement for expenses incurred in connection with the use of [medical] equipment, supplies or services."); [**60] *see also Nat'l Ass'n of Patients on* Hemodialysis & Transplantation, Inc. v. Heckler, 588 F. Supp. 1108, 1128 (D.D.C. 1984) (explaining that Congress' decision to allow Medicare to pay conditionally when group health plan was not expected to render prompt payment "was a response to the conferees' concern about patient anxiety regarding the source of promptness of payment and delays in reimbursement"); *Brown*, 252 F. Supp. 2d at 319 ("The sole purpose of the phrase 'reasonably expected to be made promptly' in *subparagraph A* is to ensure that needed Medicare payments are not delayed to the detriment of a Medicare beneficiary"). It is for that reason that, even where Medicare reasonably anticipates that another insurer will pay eventually, it may pay conditionally if the dispute over primary coverage is likely to last more than 120 days.

[**61] Although the agency interpretation finds overwhelming support in the congressional purpose and legislative history, the case law has been less uniform. Several courts have accepted Defendants' view that Medicare's payment is conditional and subject to

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[16] To the extent that there is any record of legislative intent at all, it indicates that Congress was dissatisfied that Medicare was not recouping as much from primary payers as it could; there is not the slightest indication of congressional sentiment that Medicare was recovering too much. See 136 Cong. Rec. S13419-01 (daily ed. Sept. 19, 1990) (statement of Sen. Roth) ("Unfortunately, performance under the MSP Program has not measured up. Failure to follow the MSP law is costing the taxpayer billions of dollars. ... Studies by the General Accounting Office and the inspector general of the Department of Health and Human Services have repeatedly identified the MSP program as gushing with leaks of Federal tax dollars."); 135 Cong. Rec. S11848-01 (daily ed. Sept. 26, 1989) (statement of Sen. Durenberger) (discussing, in context of FY 1990 appropriations bill for health agencies, inadequacy of expenditures by Medicare intermediaries on MSP recoupment activity). In the 1989 OBRA legislation containing the confusing passage which is the subject of this dispute, Congress simultaneously enacted measures augmenting Medicare's ability to identify the existence of primary coverage, by giving HHS access to data from the IRS and the Social Security Administration. In so doing, Congress indicated in its statement of intent that under current law, HHS is unable to identify all Medicare secondary payer situations, principally because HHS is unable to identify cases in which Medicare beneficiaries have primary coverage through a spouse's plan." H.R. Rep. 101-247, at 1021, *reprinted in* 1989 U.S.C.C.A.N. 1906, 2492 (1989). Nothing in the statement of intent indicates a desire to restrict Medicare's ability to recover conditional payments, or a realization that the 1989 amendments would be so construed.

[17] Suppose, for instance, that a Medicare patient was injured as the result of a multi-party automobile accident in which each motorist carried private insurance, yet each insurer refused to pay until liability could be sorted out among the participants. Even though it was certain that some insurer would ultimately pay - the only question being which - Defendants' interpretation would deprive Medicare of the ability to lay claim to the insurance proceeds if Medicare made a conditional payment on the basis that private payment was not "promptly" forthcoming.

recoupment only in the circumstances described in one portion of *subparagraph (A)*: the rightful primary insurer has paid, or is expected to do so promptly. See *In re Dow Corning Corp*, 250 B.R. 298, 348 (Bankr. E.D. Mich. 2000); *Brown v. Am. Home Prods. Corp. (In re Diet Drugs Prods. Liab. Litig.)*, 2001 U.S. Dist. LEXIS 2959, No. MDL 1203, Civ.A. 99-20593, 2001 WL 283163 at * 11 n.20 (E.D. Pa. March 21, 2001); *In re Orthopedic Bone Screw Prod. Liability Litig.*, 202 F.R.D. 154, 167-68 (E.D. Pa. 2001). [18]

[**62] However, in *Cochran v. United States Health Care Fin. Admin.*, 291 F.3d 775 (11th Cir. 2002), our dicta read the statute in accordance with the Government's more expansive view. See *id.* at 777 ("In order to accommodate its beneficiaries ... Medicare does make conditional payments for covered services, even when another source may be obligated to pay, if that other source is not expected to pay promptly."). That is the way most other courts have interpreted it. See *Rybicki v. Hartley*, 792 F.2d 260, 262 (1st Cir. 1986) [*893] (Breyer, J.) ("Taken literally, [the MSP] simply says (in respect to a Medicare subscriber with a private source of insurance), if we can be reasonably certain that the insurance company will pay, Medicare won't pay; if we cannot be certain, Medicare will pay, but then, if the company pays you, you must reimburse Medicare.'") (parenthetical in original); accord *Evanston Hosp. v. Hauck*, 1 F.3d 540, 544 (7th Cir. 1993) (citing Rybricki, "the Medicare law ... forbids payment where a third party can reasonably be expected to make prompt payment," and conversely, Medicare is allowed to pay conditionally where contested tort litigation [**63] cannot be expected to yield prompt payment); *Smith v. Farmers Ins. Exchange*, 9 P.3d 335, 338-39 (Colo. 2000) (en banc); *Brown*, 252 F. Supp. 2d at 317; *Oregon Ass'n of Hospitals v. Bowen*, 708 F. Supp. 1135, 1140-41 (D. Ore. 1989); *Vogt v. Wausau Hosps.*, 516 N.W.2d 791, 184 Wis. 2d 404, 1994 WL 246552 at * 2 (Wis. Ct. App. 1994); see also Thomas J. Nyzio, *Medicare Recovery in Liability Cases*, S.C. LAWYER, May/June 1996, at 20, 21-22 ("Under the statute, payment may not be made with respect to any item or service to the extent that payment has been made, or prompt payment... can reasonably be expected to be made, under a liability or no fault insurance policy or plan. However, payments can be made in the event that a provider will not receive prompt payment from a third party payer or from the proceeds of a liability settlement or judgment. These payments, however, are conditioned on reimbursement to Medicare in the event that payment for the same services is received from a liability or no fault insurer.") (citations omitted); Susan G. Haines & Tomas D. Begley, Jr., *Workers' Compensation Medicare Set-Aside Trusts*, ABA Brief/Practice [**64] Tips (Fall 2001) ("Medicare may make a conditional payment for services if Medicare does not reasonably expect the third-party insurer to make its primary payment promptly.").

In summary, we conclude that the agency's interpretation is eminently reasonable. Indeed, the agency's interpretation follows the most plausible interpretation of the statutory language, and is the only construction of the language which is consistent with the clear statutory purpose. Both the legislative history and the uninterrupted history of revisions to the MSP statute support this interpretation. We have no doubt that ***HN28*** payments made by Medicare on behalf of breast-implant patients were conditioned upon reimbursement if the patients later recovered from one of the primary sources enumerated in *42 U.S.C. § 1395y(b)(2)(A)*.

> 2) Do the RSP Defendants qualify as "self-insured," so that their payments to the class members were made "under a primary plan" and thus subject to a recoupment action under the MSP statute?

The Government contends that the RSP Defendants are liable under the MSP statute on the basis that they operated

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[18] In Thompson v. Goetzmann, 315 F.3d 457 (5th Cir. 2002), the Fifth Circuit originally accepted the premise that the Government's right of recovery under the MSP was limited to situations in which another primary coverage source had paid or was expected to pay promptly. See id. at 468. Upon the Government's petition for rehearing en banc, however, the panel withdrew its opinion and issued an amended opinion which, while reaching the same ultimate result, no longer relied upon the limited construction of subparagraph (A) that Defendants advance here. See Thompson v. Goetzmann, 337 F.3d 489 (5th Cir. 2003) (amending initial Goetzmann decision). In a preface to the amended opinion, the court stated that, while it remained convinced that the statute's wording supported its original conclusion that the Government may not collect from a primary plan unless such plan is expected to pay promptly, it recognized that its interpretation risked producing an "absurd result ... [that] precludes the right to reimbursement from any disputed or potentially disputed funds," since a disputed fund could never be expected to pay promptly. See id. at 492. We agree with the most recent Fifth Circuit opinion that the interpretation urged by Defendants, and accepted by the courts cited above, produces an absurd result. Moreover, we point out in the text above that this result is not indicated by the plain language of the statute. Rather, our construction is a much more plausible construction of the plain language of the statute.

under a "self-insured plan." [19] The parties dispute [**65] whether the Government's Complaint alleged the existence of a self-insured plan with sufficient detail. In its opinion, 174 F. Supp. 2d at 1254-55, the district court expressed its relevant holdings in several [*894] articulations, which we number for ready reference:

> (1) that a "'self-insured plan' connotes some type of formal arrangement ..."
> (2) " ... by which funds are set aside and accessed to cover future liabilities;"
> (3) "Payments [by a tortfeasor], without more, [do not] constitute a 'plan' of self-insurance;"
> (4) "The mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance" (quoting 54 Fed. Reg. 41727 (Oct. 11, 1989); and
> (5) "Payments of deductibles ... do not constitute a 'plan' of self-insurance." We agree with the district court as to the first, third and fourth holdings, but not as to the second and fifth.

[**66] There is remarkably little legal authority (none binding in our Circuit) categorically defining what it means to operate a "self-insurance plan." Black's Law Dictionary defines "self-insurance" as: "The practice of setting aside a fund to meet losses instead of insuring against such through insurance. A common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance." BLACK'S LAW DICTIONARY 1220 (5th ed. 1979). The first sentence of the dictionary definition suggests that an advance set-aside of funds would usually be a part of a self-insurance plan. [20] See Jackson v. Donahue, 193 W. Va. 587, 457 S.E.2d 524, 528 (W.Va. 1995) ("The phrase 'self-insurance' means, generally, the assumption of one's own risk and, typically, involves the setting aside of a special fund to meet losses and pay valid claims(.)"); COUCH ON INSURANCE 3D § 10:1 (stating that, while "the term 'self-insurance' has no precise legal meaning," it generally implies "the same sort of underwriting procedures that insurance companies employ," such as estimating likely losses and setting aside reserves).

[**67] Other authorities, however, suggest a more elastic definition. See In re Amatex Corp., 107 B.R. 856, 872 (Bankr. E.D. Pa. 1989) ("Self insurance is best compared to the familiar 'deductible' amount referenced in most insurance policies. It is common knowledge to anyone who has ever filed an insurance claim subject to same that the deductible must be exhausted before the liability of the insurer begins."); 22 APPLEMAN ON INS. 2d § 140.5 (Eric Mills Holmes, ed., 2003) at 407 n.67 ("True self-insurance occurs when an entity retains all risks against which it might otherwise insure. This type of self-insurance is popular among governmental entities as a result of statutory immunity or costs. Another type of self-insurance occurs when an entity purchases liability insurance for a certain limit and any amount of exposure thereof is retained by the entity."); see also Sears, Roebuck & Co. v. IRS, 972 F.2d 858, 861 (7th Cir. 1992) (stating, in context of dispute over tax treatment of insurance transaction between related corporate entities, that "self-insurance' is [*895] just a name for the lack of insurance - for bearing risks oneself."); Beech Aircraft Corp. v. United States, 797 F.2d 920, 922 (10th Cir. 1986) [**68] (stating, in tax case similar to Seventh Circuit's Sears, Roebuck, that "self-insurance is not the equivalent of insurance. If one having an insurable risk retains the risk of his own loss, there is no risk transfer, and the arrangement is self-insurance."); In re North American Royalties, Inc., 276 B.R. 860, 864 (Bankr. E.D. Tenn. 2002) (holding, in construing contract of insurance, that "the term 'self-insured' means that the plan sponsor... does not have insurance; it pays the expenses from its income."). These and other authorities strongly indicate that "self-insurance" is an unscientific and imprecise term, the interpretation of which varies with the context.

Our understanding of what it means to operate under a "self-insured plan" is informed by HHS regulations, to

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[19] The Government concedes that the RSP settlement mechanism, which antedated the Government's Medicare payments, is not a "self-insured plan" as that term is understood in 42 U.S.C. § 1395y(b)(2)(A)(ii). Rather, the Government's theory is that the individual companies were each operating under a plan of self-insurance in which they arranged to purchase third-party liability coverage and self-insure up to the amount of their policies' deductibles.

[20] However, the second sentence is not inconsistent with the commonly understood practice of self-insuring up to a certain amount, and then covering any excess with insurance, often with no set-aside of funds.

A more recent edition of Black's defines "self-insurance" as simply: "A plan under which a business sets aside money to cover any loss." The same edition defines "self-insured retention" as: "The amount of an otherwise-covered loss that is not covered by an insurance policy and that [usually] must be paid before the insurer will pay benefits." BLACK'S LAW DICTIONARY 807, 1365 (7th ed. 1999). This definition, like its predecessor, suggests that self-insurance can be understood both as the practice of setting aside a reserve to pay claims, and the practice of paying a deductible before third-party coverage becomes effective.

which - because of Congress' express delegation and the agency's recognized expertise in the area - we are duty-bound to defer if they are reasonable. *HN29* For purposes of the MSP statute, HHS regulations define a "plan" of insurance as including "any arrangement, oral or written, by one or more entities, to ... assume legal liability for injury or illness." 42 C.F.R. § 411.21 [**69] . Inclusion of the term "oral" suggests an intent to reach informal, *ad hoc* arrangements in addition to traditional insurance policies; obviously, no standard insurance company issues coverage verbally. In addition, the regulations provide the following definition of a "self-insured" plan: a "self-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier." 42 C.F.R. § 411.50(b).

HHS has purposefully adopted a broad definition of what it means to be self-insured. For instance, the agency does not limit its definition to plans that are certified to operate as self-insurers by state insurance regulators. In enacting its inclusive definition, the agency explained that to do otherwise would enable a responsible party to elude MSP liability by paying a claim out of pocket instead of submitting the claim to its liability insurer - a mechanism not unlike the RSP compensation process here. See Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 53 Fed. Reg. 22335, 22339-40 (proposed June 15, 1988). Of particular significance [**70] here, *HN30* HHS has expressly defined a "liability insurance payment" for purposes of the MSP statute to include: "A payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan." 42 C.F.R. § 411.50(b).

The agency's view is especially persuasive in the absence of a universally accepted and authoritative definition of "self-insured plan" which Congress might have contemplated in drafting the statute. Thus, the district court's first articulation - that a self-insured plan connotes some type of *ex ante* arrangement to assume legal liability for medical expenses - is consistent with the regulation, to which we agree deference is due. [21] For the same reason, we agree that the district court's third articulation - that a tortfeasor's mere payment, without more, would not constitute a plan of self-insurance - is consistent with the regulations, as is its fourth - that [*896] the mere absence of insurance does not necessarily constitute a plan of self-insurance. See Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41727 [**71] (Oct. 11, 1989) ("We note that the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance."). In other words, without a plan or prearrangement, there can be no self-insured plan. [22]

[**72] However, it is apparent from the foregoing quotations from the regulations that the district court's second and fifth holdings are inconsistent with the regulations. The district court's fifth holding is squarely inconsistent with the regulation's affirmative provision that a "liability insurance payment" includes "an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any entity that carries liability insurance or is covered by a self-insured plan." 42 C.F.R. § 411.50(b). There is nothing in the plain meaning of the statute which might preclude the agency's interpretation to include within the self-insured concept the commonly occurring circumstance of an individual or entity planning ahead of time to assume responsibility and liability for certain risks up to a designated amount, and to procure an insurance policy to cover the excess. As we have seen, the relevant statutory term "self-insured plan" has no precise legal meaning, seems to be interpreted by some authorities more rigidly, but is interpreted by other authorities to include precisely such a combination of self-insurance up to a certain [**73] amount with the excess to be covered by an insurance policy. Consistent with the latter authorities, common experience teaches

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[21] To the extent that the district court meant by its term "formal" arrangement something more than that the arrangement must be *ex ante* and must be an arrangement, albeit oral, to assume legal liability or pay for medical expenses, the district court would have required more than the regulations; we see no warrant for requiring more.

[22] We see no tension between our position and that in the cases cited by Defendants, United States v. Philip Morris, Inc., 116 F. Supp. 2d 131 (D.D.C. 2000), and Mason v. American Tobacco Co., 212 F. Supp. 2d 88 (E.D.N.Y. 2002). In each case, the district court dismissed MSP claims seeking Medicare reimbursement from tobacco companies accused of tortiously injuring their customers. In Philip Morris, the Government's claim was found flawed because it merely made the conclusory allegation that the defendants were "responsible" for payment under the MSP without advancing a basis - and, specifically, without alleging the existence of a coverage plan. Id. 116 F. Supp. 2d at 146. In Mason, the plaintiffs' claim rested solely on the theory that a large corporation without insurance that was accused of inflicting a tortious injury was, by definition, operating a self-insured plan. There was no suggestion that the tortfeasor had purchased supplemental insurance and made arrangements to cover the deductible out of its own funds. See id. at 92. We agree with these courts to the extent that they hold that the MSP requires the existence of some sort of plan as opposed to a mere *post hoc* assumption of liability.

us that planning such a combination of deductibles and insurance policies is often referred to as self-insurance. Because the statute has no unambiguous meaning in this regard, deference is due to the regulation, and the district court's contrary holding cannot stand.

We also disagree with the district court's second holding, that self-insurance requires a set-aside of funds to cover the risks assumed. Even the sparse legal authority which suggests that there usually will be a reserve for losses; also indicates that "self insurance" has no precise legal meaning. Other authorities suggest there is no absolute need for a set-aside of funds. We see no basis in the statute or in any well-established meaning of the statutory term "self-insured plan" to conclude that the term unambiguously requires a set-aside of funds. Thus, we look to the regulations. We conclude that *HN31* an absolute requirement that funds be set aside is plainly inconsistent with the thrust of the regulations: that a self-insurance plan encompasses any arrangement, even [*897] an oral one, to assume such [**74] risks, 42 C.F.R. § 411.21; and that it encompasses the combination of deductibles and insurance policies discussed above, which in common experience often do not include a set-aside of funds. 42 C.F.R. § 411.50(b). See also 42 C.F.R. § 411.50(b) (defining "self-insured plan" as a plan to carry one's "own risk instead of taking out insurance," a definition requiring only a "plan" and no other formalities). [23] There being no unambiguous requirement in the statutory term "self-insured plan" that a set-aside of funds is necessary, and the same being plainly inconsistent with the thrust of the regulations, we vacate the district court's holding requiring a set-aside as a prerequisite for a "self-insured plan."

[**75] We recognize that the Fifth Circuit in *Thompson v. Goetzmann*, 315 F.3d 457 (5th Cir. 2002); *opinion withdrawn and reissued as amended on other grounds*, 337 F.3d 489 (5th Cir. 2003), extensively discussed the meaning of a self-insured plan in this statute, and concluded that "a 'primary plan' of 'self-insurance' requires an entity's *ex ante* adoption, for itself, of an arrangement for (1) a source of funds, and (2) procedures for distributing these funds when claims are made against the entity." Id. at 463.

We note first that we fully agree with the Fifth Circuit that the term "plan" in the statutory term "self-insured plan" clearly contemplates an *ex ante* arrangement. This is clear in both the statute and the regulation. It is probable that this is the extent of the holding in Goetzmann, and that the balance of the foregoing quotation from the Fifth Circuit case is dicta. Apparently the only issue in Goetzmann was whether a single, discreet, settlement by a tortfeasor with a single plaintiff whereby the tortfeasor paid the plaintiff with its own funds, without more, constituted a "self-insured plan." [24] We agree with this [**76] holding because that circumstance would not entail a "plan" or *ex ante* arrangement. It is probable therefore that what the Fifth Circuit said about setting aside funds and procedures is dicta. [*898]

[**77] We respectfully disagree with the *Goetzmann* dicta to the effect that there cannot be a self-insured plan absent a setting aside of the funds and formal procedures. We agree with Goetzmann that the statutory term

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[23] The Defendants' suggestion that the word "instead" means that "self-insurance" can exist *only* in an arrangement including no insurance is wholly without merit. Not only would that be a grudging construction of the language, it would be inconsistent with the thrust of 42 C.F.R. § 411.50(b), which contemplates a combination of insurance policies and deductibles, and with the clear weight of authority that an entity can self-insure for a designated amount and purchase coverage for liability exceeding the designated amount. See, e.g., BLACK'S LAW DICTIONARY 1220 (5th ed. 1979) (explaining, in defining self-insurance, that "[a] common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance.").

[24] The following quotations from Goetzmann indicate that these were the facts, thus defining the holding:

> . "We" ... also agree with the other district courts that have concluded that an alleged tortfeasor who settles with a plaintiff is not, ipso facto, a 'self-insurer' under the MSP statute." Id. at 462.
> . "It is wrong for the government to contend that an entity's negotiating of a single settlement with an individual is sufficient, in and of itself, for such entity to be deemed as having a 'self-insurance plan.'" Id. at 463 (emphasis in original).
> . "Nowhere does the MSP statute mention or even suggest that an alleged tortfeasor who settles a single claim with a single plaintiff falls within the ambit of the statute's category of a 'self-insurance' plan." Id. at 464.
> . "But [the defendant] has only negotiated a discreet settlement with a single plaintiff and paid that plaintiff accordingly. It is simply a non sequitur for the government to infer from 'payment responsibility' in tort a preexisting primary plan of self-insurance." Id. at 465 (emphasis in original).

"self-insured plan" should be read in the context of a "primary plan." However, especially because the statutory definition of a primary plan expressly includes self-insured plans, we see nothing in that context requiring either a set-aside of funds or formal procedures. See 42 U.S.C. § 1395y(b)(2)(A) ("In this subsection, the term 'primary plan' means ... a workman's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no-fault insurance") (parenthetical in original). We gather from the Fifth Circuit opinion that it derived its concept of the scope and limit of the term "self-insured" from the "ordinary meaning" of that term, which it derived in turn from several legal authorities, principally the Couch treatise. However, as noted above, even the legal authority relied upon by Goetzmann acknowledged that there was no precise legal meaning, and while some authorities suggest [**78] that a set-aside of funds and formal procedures often accompany self-insured plans, other authorities, as noted above, suggest otherwise. Goetzmann does not alter our conclusion that there is no precise legal meaning for the statutory term "self-insured plan" that is well-established enough to rise to the level of rendering a statutory term unambiguous. [25] Accordingly, it is appropriate to look to the regulations to which we owe deference. [26]

[**80] Applying the foregoing principles to the instant complaint, it is here alleged [*899] that "the RSP defendants were self-insured against the risk of products liability claims by breast implant recipients, and paid such claims from self-insured funds or retained earnings." The allegation that the Defendants self-insured "against the risk ... of claims" indicates that the plan or arrangement existed before the claims did, thus satisfying the requirement of an *ex ante* arrangement to assume legal liability. Moreover, there are suggestions in the record that the plan or arrangement may have included a combination of self-insurance with respect to certain amounts and the purchase of insurance policies as to other amounts, precisely the kind of combination of deductibles and insurance policies deemed by the regulations to constitute a self-insured plan. We readily conclude that, with respect to the self-insured plan issue, the allegations are sufficient to survive a challenge under *Rule 12(b)(6)*. [27]

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[25] The Goetzmann court also rejected the Government's argument that the statute was ambiguous. Again, however, it appears likely that the court was focusing on the precise facts of the case and its narrow holding - that a discreet settlement by a single tortfeasor out of its own funds would not by itself (that is, without any prearrangement or plan) constitute a self-insured plan. This seems likely because, as discussed above, there is no precise legal meaning of the statutory term sufficiently well-established to rise to the level of rendering it unambiguous with respect to the Goetzmann dicta to the effect that a set-aside of funds and formal procedures are required. In other words, the statute may well be unambiguous with respect to the requirement of a plan or *ex ante* arrangement, but it is not with respect to the Goetzmann dicta. To the extent the Fifth Circuit intended to hold otherwise, we respectfully disagree.

[26] We note that the Goetzmann court relied heavily on a questionable assumption regarding the interaction of the MSP statute and the aforementioned Medical Care Recovery Act, 42 U.S.C. § 2651. Because the express purpose of the MCRA is to impose liability upon tortfeasors to repay the Government for the reasonable value of health care furnished to a tortiously injured party, the Goetzmann court found that reading tortfeasor liability into the MSP "would, in effect, eliminate the need for the MCRA, or at least condemn some of Congress' language in the MCRA to the scrap heap of surplusage." Id. at 465. However, the Goetzmann reasoning does not resolve this perceived conflict, as it would itself render superfluous that portion of the MSP statute imposing liability on an entity "required or responsible" to pay under a "primary plan" of self-insurance - i.e., a self-insured tortfeasor. The Goetzmann view would also render superfluous a substantial portion of the Government's subrogatory right conferred by the MSP statute, because establishing the liability of the patient's insurer to Medicare necessarily may require bringing a subrogation action against the tortfeasor. Moreover, Goetzmann's perception of an overlap between the coverage of the MCRA and the MSP may be in error. See United States v. Philip Morris, Inc., 116 F. Supp. 2d 131, 140-44 (D.D.C. 2000) (holding, after extensive analysis of statute's legislative history, that MCRA applies exclusively to federal health care expenditures other than Medicare, such as coverage for military personnel and their dependents); accord In re Diet Drugs, 2001 U.S. Dist. LEXIS 2959, Nos. MDL 1203, CIV.A. 99-20593, 2001 WL 283163 (E.D. Pa. March 21, 2001) at *7-*8.

[27] We discern no merit in the argument pressed by the Steering Committee intervenors that the RSP Defendants' payments are excepted from the reach of the MSP statute because they are not directly pegged to the amount of health care expenses incurred by the class members. Courts have uniformly concluded that a settlement agreement that includes a non-itemized element of compensation for a plaintiff's medical care is "for" medical expenses, even if the exact share or amount is indeterminate. See Share Health Plan of Illinois, Inc. v. Alderson, 285 Ill. App. 3d 489, 674 N.E.2d 69, 72, 52 M.S.P.R. 472, 220 Ill. Dec. 798 (Ill. App. Ct. 1996) (holding that HHS can recover Medicare payments from beneficiary's lump-sum settlement of tort claim "regardless of whether and how amounts are designated"); see also Wilson v. State, 142 Wn.2d 40, 10 P.3d 1061, 1067 (Wash. 2000) (en banc) (finding that state Medicaid lien attached to entire amount of patient's medical malpractice settlement, not just amount earmarked for medical expenses); accord Calvanese v. Calvanese, 93 N.Y.2d 111, 710 N.E.2d 1079, 1082, 688 N.Y.S.2d 479 (N.Y.

[**81] 3) Can the RSP Defendants be forced to repay Medicare, when it is undisputed that they had no actual knowledge of Medicare's specific payments on behalf of particular beneficiaries? [28]

[**82] The Government argues that the district court erred in dismissing the Government's subrogation claim pursuant to *Rule 12(b)(6)*. As both parties and the district court understood, the Government clearly has subrogation rights to obtain reimbursement of its conditional payments. *Section 1395y(b)(2)(B)(iii)* provides:

> *HN32* (iii) Subrogation rights
>
> The United States shall be subrogated (to the extent of payment made under [*900] this subchapter for an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

In granting the *Rule 12(b)(6)* dismissal, the district court rejected the Government's subrogation claim, apparently either requiring proof that the RSP Defendants actually knew they were paying tort claimants whose medical expenses had already been paid by Medicare, or applying an unrealistically strict perception of constructive knowledge. At one point, the district court said that the Government had affirmatively pled facts defeating its claim, in that its complaint acknowledged that the RSP Defendants "did not ascertain" whether any of the tort claimants to be paid had actually [**83] received Medicare benefits. We reject this ground without need for further discussion; in effect, the district court required actual knowledge, and we hold that constructive knowledge is sufficient. Our discussion henceforth will focus on constructive knowledge.

HN33 We presume that Congress legislates against the backdrop of established principles of state and federal common law, and that when it wishes to deviate from deeply rooted principles, it will say so. See *United States v. Texas*, 507 U.S. 529, 534, 113 S. Ct. 1631, 1634-35, 123 L. Ed. 2d 245 (1993) ("Statutes which invade the common law ... are to be read with a presumption favoring the retention of long-established and familiar principles, except when a statutory purpose to the contrary is evident. In such cases, Congress does not write upon a clean slate. In order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law.") (internal quotes and citations omitted). *HN34* It is well established at common law that a tortfeasor that pays a settlement to a claimant with knowledge - *actual or constructive* - that another entity has a subrogation claim against the [**84] proceeds is not insulated from suit by the subrogee by virtue of the incorrect payment. See *Dadeland Dodge, Inc. v. American Vehicle Ins. Co.*, 698 So. 2d 929, 931 (Fla. Dist. Ct. App. 1997) (holding that tortfeasor that has constructive knowledge of insurer's perfected right of subrogation cannot rely on insured's release to preclude insurer's claim for reimbursement); accord *State Farm Fire & Cas. Co. v. Pacific Rent-All, Inc.*, 90 Haw. 315, 978 P.2d 753, 770 (Hawaii 1999); *Aetna Cas. & Surety Co. v. Norwalk Foods, Inc.*, 125 Misc. 2d 986, 480 N.Y.S.2d 851, 852 (N.Y. Civ. Ct. 1984); see also *Poole Truck Line, Inc. v. State Farm Mut. Auto. Ins. Co.*, 163 Ga. App. 755, 294 S.E.2d 570, 571-72 (Ga. Ct. App. 1982) (because state law makes no-fault automobile coverage mandatory, tortfeasor can be charged with constructive knowledge that motorist carried insurance and that motorist's insurer had a statutory right of subrogation, thus precluding tortfeasor from invoking its settlement with injured motorist to bar insurer's subrogation claim).

In a case involving the Government's subrogation rights under this same statutory [**85] provision, the D.C. Circuit has held that a party, standing in the shoes filled by the RSP Defendants in this case, can avoid reimbursing Medicare under the instant statutory provisions only if its payment to the wrong party was made without knowledge (either actual or constructive). *HIAA*, 23 F.3d at 418 ("If a third party payor wants to avoid having to make two payments for the same service,

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1999). That interpretation is consistent with HHS' own understanding. See Medicare Program; "Without Fault" and Waiver of Recovery from an Individual as it Applies to Medicare Overpayment Liability, 63 Fed. Reg. 14506, 14514 (proposed March 25, 1998) ("Since liability payments are usually based on the injured or deceased person's medical expenses, liability payments are considered to have been made with respect to' medical services related to the injury even when the settlement does not expressly include an amount for medical services.").

[28] At the outset, we agree with the district court that dismissal was not warranted on the grounds that the Government failed to plead that it attempted to recoup its duplicate payments from the Medicare beneficiaries in the plaintiff class before seeking recoupment from the Defendants; it was adequately pled. We decline to address and express no opinion on the merits of Defendants' argument that the Government is obligated to seek reimbursement first against each member of the plaintiff class before pursuing reimbursement from the RSP Defendants, because the issue is not necessary to our holding, and because the issue was inadequately addressed by the district court and inadequately briefed on appeal. The Defendants are free to assert this argument on remand, and the district court should address it anew after appropriate development of the record and briefing with respect to the agency's policies and practices, and with respect to the relevant statutes, regulations, and other authorities.

it should refrain from paying someone whom it knows or should know that HCFA already has paid."). Further defining the content of constructive knowledge in the instant context, the D.C. Circuit cited with approval the agency's interpretation that constructive [*901] knowledge is satisfied when the third-party payor has in its possession direct information that Medicare has made a conditional payment, or has in its possession information necessary to draw the conclusion that Medicare has made such a payment. [29] The D.C. Circuit interpreted the latter reference to mean that third-party payors would be expected to draw certain inferences based on published Medicare procedures. Id.

[**86] We believe that the constructive knowledge standard is fully consistent with the intent of the MSP statute, and indeed necessary if the statute is to fulfill its purpose. The overriding purpose of the MSP statute was to allocate primary responsibility for the payment of claims to private insurance, where available.

Between two sources of coverage, the insurer that pays second is in the superior position to prevent an erroneous or misdirected payment. The first payer can avoid such an outcome only by refusing to pay at all.. Congress foreclosed that option in *42 U.S.C. §§ 1395y(b)(2)(A) and (b)(2)(B)* by providing for Medicare to pay first where payment from the primary insurer was not reasonably forthcoming. When Medicare pays, therefore, it is paying "in the dark" - it does not know, and *cannot* know, whether someone else will pay. [30] By contrast, when the primary insurer later pays, Medicare's prior payment will normally be a matter of ascertainable fact.

[**87] In light of the well-established common law of subrogation, consistent with the purposes of the MSP statute, and following the D.C. Circuit, we hold that either knowledge or constructive knowledge is sufficient. Thus, *HN35* if the RSP Defendants had either knowledge or constructive knowledge that some of the recipients of the funds they were paying out had received breast implant-related medical treatment for which Medicare already paid, then the RSP Defendants would be [*902] liable to reimburse the Government pursuant to *§ 1395y(b)(2)(B)(iii)*.

We need not at this early stage of the litigation attempt to define the precise scope of the constructive knowledge that will trigger liability, because we conclude that the Government's allegations in that regard survive *Rule 12(b)(6)*. [31] The Government has alleged that the RSP Defendants structured the settlement in a manner so as to avoid learning any identifying information about the class members, including their Medicare eligibility. *HN36* A party that willfully blinds itself to a fact, as the Complaint here alleges occurred, can be charged with constructive knowledge of that fact. [32] See *Williams v. Obstfeld*, 314 F.3d 1270, 1278 (11th Cir. 2002) [**88]

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[29] The HIAA definition of constructive knowledge is essentially identical to that proffered by Defendants from the affidavit of HHS administrator Paul J. Olenick, which the Government submitted in HIAA as its statement of when HHS will consider an insurer to have the requisite knowledge to trigger liability under 42 C.F.R. § 411.24(i)(2). See Def. Ex. B ("A third party payer 'learns' of a Medicare conditional primary payment when it receives information which makes it aware, or should make it aware, that Medicare has made a conditional primary payment. This would be the case when the third party payer receives direct information that Medicare has made a conditional payment or when it receives the information necessary to draw the conclusion that Medicare has made a primary payment.") (emphasis in original).

[30] HHS and Congress have repeatedly flagged Medicare's inability to ascertain the existence of alternative sources of coverage as a weakness in the secondary payer program. See, e.g., Dept. of Health and Human Serv., Office of the Inspector Gen. ("HHS IG"), Survey of Medicare Payments to Workers' Compensation Recipients in the State of Florida, No. A-04-01-07003 (January 2003) at 6 ("Unfortunately, the system as currently structured does not provide a standard procedure that ensures that Medicare is informed of all [workers' compensation] settlements"); HHS IG, Medicare Prepayment Review: MSP Procedures at Carriers, No. OEI-07-89-01683 (August 1991) at 2 (citing estimate that, based on random sampling of processed by private contractors, "Medicare lost in excess of $ 600 million in FY 1988 due to unidentified primary payment sources"). Overlapping coverage is particularly difficult to detect where, as here, the Medicare payment and the insurance payment go to different recipients (Medicare's to the doctor or hospital, and the alleged tortfeasors' directly to the patient). In light of this well-recognized weakness, it is therefore reasonable for the agency to interpret the MSP, and Congress' subsequent revisions of it, as imposing the risk of loss on the alternative payer for failing to determine whether Medicare has already paid for the same service.

[31] We note that the Federal Rules provide that the *HN37* defendants' knowledge is an element that "may be averred generally," thus eschewing the particularity standard that applies to other mental-state elements (fraud, mistake) under Rule 9. See Fed. R. Civ. P. 9(b).

[32] We need not at this stage decide the significance of the facts that might be developed in this regard. However, it is clear that a party should not be able to avoid constructive knowledge and shield itself from statutory liability by consciously avoiding information which would constitute constructive knowledge and result in liability. In addition to facts that might be developed in this regard on remand, the district court might also address the relevance and significance of knowledge in fact obtained during the claims process, and whether such knowledge should be imputed to the RSP Defendants or whether they should be deemed to

(stating in context of civil RICO action that "under the doctrine of willful blindness or deliberate ignorance, which is used more often in the criminal context than in civil cases, knowledge can be imputed to a party who knows of a high probability of illegal conduct and purposely contrives to avoid learning of it."); CFTC v. Sidoti, 178 F.3d 1132, 1136-37 (11th Cir. 1999) (holding, in context [*903] of commodities fraud action, that "the element of knowledge may be inferred from deliberate acts amounting to willful blindness to the existence of fact or acts constituting conscious purpose to avoid enlightenment."). The Complaint therefore sufficiently alleges constructive knowledge, despite the Government's concession that the Defendants did not acquire actual knowledge of Medicare's conditional primary payments. [33]

For all of the foregoing reasons, we conclude that the Government's allegations of constructive knowledge are sufficient, and the Government's subrogation claim under § 1395y(b)(2)(B)(iii) survives the Rule 12(b)(6) challenge. [34] [*904]

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have consciously avoided same. At this early stage, and without development of the relevant facts, analysis by the district court, or adequate briefing from the parties, we decline to address this issue further and express no opinion as to its resolution.

In this regard, the parties have discussed whether an entity standing in the shoes of the RSP Defendants has a duty to investigate for the benefit for the Government to discover Medicare's involvement. The discussion of the parties revolved around 42 C.F.R. § 411.25(a) ("If a third party payer learns that [HHS] has made a Medicare primary payment for services for which the third party payer has made or should have made primary payment, it must give notice to that effect to the Medicare intermediary or carrier that paid the claim."). In light of our decision that the Government's allegations survive Rule 12(b)(6), and in light of the discovery that will be available to the Government on remand that may reveal to the Government any information that investigation by the Defendants could have yielded, thus possibly mooting the duty-to-investigate issue, we decline to address it at this stage. To the extent that the district court's discussion (see In re Silicone Gel, 174 F. Supp. 2d at 1257) constitutes a holding that Medicare cannot interpret § 411.25(a) to require an insurer to inquire into the existence of a prior Medicare payment, we note that the district court did not address whether the agency had interpreted its regulation, or the significance thereof. See, e.g., Medicare Program; Medicare Secondary Payment, 59 Fed. Reg. 4285, 4286 (Jan. 31, 1994) (explaining the statute and regulations concerning third-party payors with primary obligations to which Medicare is secondary, and suggesting pursuant to 42 C.F.R. § 411.25 that where there has been delay in paying by the primary obligor, it should assume that Medicare made a conditional payment: "A beneficiary who is eligible for Medicare files a claim for primary payment with a third party payer, the claim is denied, the beneficiary appeals, and the denial is reversed. (The third party payer should assume that Medicare made a conditional primary payment in the interim.)"). If the duty to investigate issue should become a live one on remand, then the district court should address the issue afresh conducting an appropriate analysis, e.g., ascertaining any relevant agency interpretation and determining the extent of Chevron deference, if any.

[33] In responding to the motion to dismiss, the Government asked the district court for leave to amend its Complaint to plead knowledge with more detail if the court were to find that knowledge was a required element at the pleading stage. The district court denied that motion, having found that the Government had no viable claim under the MSP regardless of how it was pled. Because we reverse the district court's legal determination as to the viability of the Government's case, the district court's reason for denying leave to amend is no longer valid and that denial is accordingly vacated.

[34] The text of Part III.B(3) of this opinion has focused only on the Government's § 1395y(b)(2)(B)(iii) subrogation claim for double payment (relating to the primary obligor's liability to reimburse Medicare even though it has already paid the Medicare beneficiary). In its brief on appeal, the Government also argued, in somewhat summary fashion, that in such situation it also has a direct cause of action for double payment pursuant to § 1395y(b)(2)(B)(ii), and that the "direct action for double payment" is not conditioned upon a determination that the primary obligor paid the Medicare beneficiary even though it knew or should have known that Medicare had already covered relevant expenses. In other words, the Government argues that § 1395y(b)(2)(B)(ii) creates a strict liability "direct cause of action for double payment." We note that the D.C. Circuit in HIAA, 23 F.3d at 417, apparently rejected this argument, inferring from the language of the statute that the Government had a claim against the "required or responsible" entity until that entity made payment, and thereafter had a claim against the person who received such payment. See42 U.S.C. § 1395y(b)(2)(B)(ii) ("The United States may bring an action against any entity which is required or responsible under this subsection to pay with respect to such item or service ... under a primary plan ... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service"). The district court, following the D.C. Circuit, rejected the Government's argument on the same ground.

We need not in this case decide whether the inference drawn by the D.C. Circuit and the district court is the only reasonable interpretation of the statute, because we reject the Government's argument in this case on other grounds. The only support for its position proffered by the Government in this case is 42 C.F.R. § 411.24(i), which provides in relevant part:

> *HN38* (i) *Special rules.* (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed [by the recipient of the

[**91] 4) Does the MSP's "double damages" provision apply to a payer that has paid the beneficiary but fails to promptly pay the Government's "double payment" reimbursement claim?

Medicare's right of action for double damages originates in *Section 1395y(b)(2)(B)(ii)*, entitled "Action by United States." It provides that *HN40* "the United States may bring an action against any entity which is required or responsible under this subsection to pay with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with *paragraph (3)(A)* collect double damages against that entity)" (emphasis added). *HN41* *Paragraph (3)(A)*, which the provision incorporates, then establishes a private cause of action for double damages "in the case of a primary plan which fails to provide [*905] for primary payment (or appropriate reimbursement) in accordance

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insurance payment] ... the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

(2) The provisions of paragraph (i)(1) of this section also apply if a third party payer makes its payment to an entity other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

However, we do not believe that the regulation supports the Government's litigation position of strict liability without regard to knowledge or constructive knowledge. The regulation indicates that a third-party payor who pays the patient is still liable for a "double payment" to Medicare in two situations: (1) when the source of the third-party payment is a liability insurance settlement or a disputed claim under group insurance or no fault coverage, or (2) when other circumstances give the third-party payor knowledge or constructive knowledge of Medicare's prior payment. Both the language of the regulation and the explanation provided by HHS in promulgating the regulation suggest that the distinction between subparagraphs (1) and (2) is not between strict liability and liability only if there is knowledge or constructive knowledge. Rather, the use of the term "disputed claims" in subparagraph (1) indicates that HHS was singling out cases in which the third party would not pay until after considerable delay - which delay, coupled with the existence of the MSP statute and regulations, HHS apparently deems to be sufficient to constitute constructive knowledge that Medicare will have made a conditional payment. The explanation provided by HHS in promulgating its final version of the rule focuses upon constructive knowledge or "awareness," and bears out this interpretation:

> We agree that when an employer group health plan (EGHP) or no-fault insurer routinely pays primary benefits on behalf of a Medicare beneficiary without knowledge of Medicare's primary payment, the insurer has acted responsibly and should not be liable for reimbursing HCFA if HCFA is unable to recover from the party that received the insurer's primary payment. However, if a third party pays an entity other than Medicare even though it was, or should have been, aware that Medicare had made a conditional primary payment, the third party must reimburse Medicare. ... Liability insurers should be aware of Medicare involvement, and therefore should not pay a claim without first checking to find out if Medicare has made conditional payments. The EGHP or no-fault insurer should be aware that, if the claim was disputed, Medicare may have made a conditional payment.

Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41721 (Oct. 11, 1989) (emphasis added). Thus, neither the language of the regulation nor the official explanation at promulgation supports the Government's assertion of strict liability in this case. Rather, the regulation and official interpretation indicate that constructive knowledge is required.

Having rejected the Government's only authority for imposing strict liability with respect to a "direct cause of action for double payment" under § 1395y(b)(2)(B)(ii), we conclude that this case should proceed with the law of the case being that *HN39* the Government must prove at least constructive knowledge to prevail in its claim for double payment under either § 1395y(b)(2)(B)(ii) or § 1395y(b)(2)(B)(iii).

As we noted in the text with respect to our discussion of the subrogation claim for double payment, we need not at this early stage of the litigation define the precise scope of constructive knowledge that will trigger liability, because constructive knowledge in the form of willful blindness has been amply pleaded in this case. Moreover, the contours of constructive knowledge were not adequately addressed by the district court and have not been adequately addressed in the briefs on appeal.

Although the district court opinion, the briefs on appeal, and this opinion have focused on the "double payment" claim, nothing in this opinion precludes the district court on remand from entertaining a Government claim pursuant to the "direct action for single payment," i.e., where the RSP Defendants have not yet paid or the RSP claimants have not yet received such payment. See 42 U.S.C. § 1395y(b)(2)(B)(ii) ("In order to recover payment under this subchapter for ... an item or service, the United States may bring an action against any entity which is required or responsible ... to pay with respect to such item or service ... under a primary plan ... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service") (parenthetical in original).

with such paragraphs (1) and (2)(A)." [35] There is no dispute that, under subparagraph (2)(B)(ii), the Government can sometimes bring a double damages action. The only disagreement is whether the qualifier "or appropriate reimbursement" empowers Medicare to recover double damages from an entity that has made its primary payment to the [**92] beneficiaries but fails to make a duplicate payment to Medicare on demand.

The district court ultimately rejected the Government's double damages claim on the same rationale that it dismissed its single damages claim. However, we have already reversed the district court's holding with respect to the Government's single damages claim. See Part III.B., *supra*. Accordingly, we also reverse the district court's dismissal of the Government's double damages claim and vacate the district court's rulings in that regard. While we expect the district court on remand to address the double damages claim on a clean slate, we offer a few comments to call attention to several pertinent matters.

We note that the statute is not clear as to when the Government is entitled to more than single damages. The statute gives the Government [**93] the right to seek double damages "in accordance with paragraph (3)(A)," see 42 U.S.C. § 1395y(b)(2)(B)(ii). Paragraph (3)(A) in turn establishes a private cause of action for double damages if a primary plan "fails to provide for primary payment (or appropriate reimbursement) in accordance with ... paragraphs (1) and (2)(A)." Paragraph (1) prohibits an employer group health plan from offering lesser coverage to employees over 65 or their spouses on the basis of their Medicare eligibility. Paragraph (2)(A) defines which sources of outside coverage will be primary with respect to Medicare. The pivotal ambiguity is in the term "reimbursement," which can plausibly refer either to the insurer's obligation to reimburse Medicare (the Government's view), or the insurer's duty to reimburse the injured party for out-of-pocket medical expenses (the Defendants' view), or both.

The pertinent regulations to which we owe deference are codified at 42 C.F.R. §§ 411.24(c)(1) and (c)(2). In these regulations, HHS draws a distinction between claims in which the insurer willingly repays Medicare versus those in which Medicare is forced to litigate. [**94] Only in the second category of cases, according to the regulations, will the Government demand double damages. The Government cited the regulations in its Complaint, but did not rely on § 411.24(c) in its briefs to the district court or here. The district court did not pass on whether the regulations were authorized by and consistent with the statute, nor - so far as we can find - has any other federal court.

Another matter to which the district court should give attention is whether the proof required to establish entitlement to double damages is the same as that required for single damages, and if that seems suggested by the statutory language, whether it makes sense in light of the statutory structure and purpose. Finally, if the same proof or standard is suggested for both single and double damages, the court should consider whether that would be inconsistent with the common-law principle that an award of multiple [*906] damages usually requires a heightened showing of wrongful intent.

5) Can either the MSP Defendants or the Escrow Agent be sued under the MSP as an entity that "received payment" from a primary plan?

The Government argues that the MSP Defendants can be sued under § [**95] 1395y(b)(2)(B)(ii) as entities that "received payment" from a primary plan, on the basis that they received payment from their liability carriers. The Government further argues that the Escrow Agent is reachable under the same provision because it received payment from the MSP Defendants and/or their insurance companies. The district court dismissed both contentions on the basis that, under the common understanding of the term "received," the statute covers only the ultimate recipient of the payments - not someone merely handling the money as a conduit.

The pertinent statutory passage provides that *HN42* "the United States may bring an action against any entity which is required or responsible under this subsection to pay... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service(.)" 42 U.S.C. § 1395y(b)(2)(B)(ii). *HN43* Under the doctrine of *ejusdem generis*, "when an enumeration of specific things is followed by some more general word or phrase, then the general word or phrase will usually be construed to refer to things of the same kind or species as those specifically enumerated. [**96] " City of Delray Beach v. Agricultural Ins. Co., 85 F.3d 1527, 1534 (11th Cir. 1996); see also Sharp v. Unlimited Concepts, Inc., 208 F.3d 928, 934 (11th Cir. 2000) ("We must interpret 'a general statutory term ... in light of the specific terms that surround it.'") (quoting Hughey v. United States, 495 U.S. 411, 419, 110 S. Ct. 1979, 1984.

[35] Paragraph (1) pertains to the responsibility of group health plans to assume primary responsibility for the coverage of their Medicare-eligible beneficiaries, and is not implicated here.

109 L. Ed. 2d 408 (1990)). [36] Applying *ejusdem generis* here, we can assume that Congress intended the term "any other entity" to be understood with reference to "physician" and "provider," and to encompass only entities of like kind.

[**97] *HN44* The agency's implementing regulation, 42 C.F.R. § 411.24(g), lists as examples of entities liable as recipients: "a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment." This list is broader than that furnished by the statute, but even the agency's examples all are entities that would be receiving payment under a claim of right or entitlement to retain it.

The Escrow Agent clearly is not of like kind to a doctor or provider. The uncontested evidence is that the Escrow Agent acts in a purely ministerial role serving the district court. All of the discretionary decisions about which claims to honor are made by the Claims Office, which is a separate entity. [37] The Escrow Agent is [*907] limited to petitioning the court if he wishes to refrain from making a payment. His only real power appears to be in making sure that the RSP Defendants continually contribute enough money to sustain the settlement fund, which does not equate to discretion over the payment of claims.

[**98] In HIAA, the D.C. Circuit invalidated as exceeding HHS' statutory authority the former 42 C.F.R. § 411.24(e), which provided that Medicare's direct right of action under 42 U.S.C. § 1395y(b)(2)(B)(ii) extended to a third-party administrator of an employer self-insurance plan as an entity charged with "making primary payment." The court held that the statute contemplated liability only for parties who were responsible *for payment*, not merely responsible for the ministerial function of *making* the payment. The court likened HCFA's interpretation to extending liability to the bank on which the health insurers benefit checks were drawn, even though the bank obviously had no discretion over whether and to whom payment was made. Id. 23 F.3d at 416-17.

In 1996, Congress amended the MSP, reinstating in part provisions struck down by HIAA. Specifically, *HN45* the 1996 amendments to § 1395y(b)(2)(B)(ii) provide that the Government "may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and [**99] is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated(.)" Although this legislation evidences congressional intent to reach third-party administrators under certain circumstances, it does not assist the Government here, since it is conceded that Gentile is an agent of the court, neither employed by nor under contract with the RSP Defendants. [38]

[**100] Finally, any analogy between the Escrow Agent and a third-party administrator is inapt. While it is true that Congress has clarified that HHS can sometimes lodge a claim against a third-party administrator even where the administrator is merely a "pass-through" who is not ultimately responsible for paying the claimant, the potential analog to a third-party administrator in our case is the Claims Office, not the Escrow Agent. A self-insurer hires a third-party administrator to do what the Claims Office is doing here: to decide who gets paid and how much. The Government, however, did not name the Claims Office or its administrator as defendants.

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[36] In Snapp, we examined a provision in the Fair Labor Standards Act, 29 U.S.C. § 216(b), providing that "any employer who violates the provisions of section 215(a)(3) of this title shall be liable for such legal or equitable relief as may be appropriate... including without limitation employment, reinstatement, promotion, and the payment of wages lost and an additional equal amount as liquidated damages." Applying the principle of *ejusdem generis*, the Snapp court held that punitive damages were entirely unlike the remedies enumerated in the statute, all of which were intended to compensate the plaintiff rather than punish the defendant; therefore, we held that punitive damages were not intended by Congress as part of the remedial scheme. Id. at 935.

[37] When a potential class member appeals the denial of her claim, the appeal goes first to the Claims Administrator and then to the district court, not to the Escrow Agent.

[38] The only case the Government cites supporting its position that a trustee-like entity could be regarded as having "received" the money it handles is King v. United States, 379 U.S. 329, 85 S. Ct. 427, 13 L. Ed. 2d 315 (1964). King arose under an entirely different statutory scheme - it evolved out of a Chapter 11 bankruptcy proceeding. The court-appointed "distributing agent" in that case (significantly, the president of the bankrupt company as opposed to a disinterested functionary) was held to be personally liable for having depleted the bankruptcy estate by paying private claims before paying the Government, because of his considerable authority to object to the way the estate was distributed. The King court strictly limited the holding to its facts. See id., 379 U.S. at 339, 85 S. Ct. at 432 ("We are not prepared to articulate any general rule defining the responsibility of distributing agents to make and press... objections [to a plan of distribution]. We hold only that King, on the facts of this case, did have such a responsibility. As president of the debtor corporation he must have been aware of the Government's potential claim(.)"). It is a considerable stretch to apply such a limited, fact-specific holding to our entirely different context.

Consequently, the district court [*908] was correct in dismissing Count VI against the Escrow Agent. [39]

[**101] We reach a different conclusion, however, as to the RSP Defendants. *HN46* Section 411.24(g) of the regulations lists an "insurer" as an example of a party that may be liable as having received payment. As we have seen, the MSP treats self-insured entities as "insurers." The structure of the underlying transaction here - the RSP manufacturers paid into the settlement fund out of their own earnings, then submitted claims to their liability carriers for partial reimbursement - is not unlike that commonly occurring in which one insurance carrier re-insures or carries excess liability coverage, thus making it both a payer (to its insured) and a recipient (in relation to its re-insurer). We believe that is the sort of arrangement HHS contemplated in including insurers and state agencies among the class of parties that could be liable on the basis of receiving payment. [40] The RSP Defendants do not argue that the regulation is invalid, and we see nothing unreasonable in the regulation as applied to this case.

[**102] The record is devoid of detail about the role of the Defendants' liability insurance carriers. If our understanding is correct - that the RSP companies initially financed the settlement, then filed claims with their insurers, which will provide reimbursement based on their independent evaluation of the class members' claims - then the district court's description of the RSP Defendants as mere intermediaries between their insurance companies and the class members is not accurate. Rather, it appears that the RSP Defendants would keep the insurance companies' payments to reimburse them for what they paid the class members. Consequently, it is conceivable that the Government could prove that the RSP Defendants "received payment" from a third party within the meaning of the statute.

6) Does the Government have a claim under the MSP statute for declaratory and injunctive relief (Counts V and VII)?

In addition to damages, the Government's Complaint sought: (1) a declaratory judgment that the RSP Defendants are liable under the MSP to reimburse Medicare for past payments to breast implant patients, and are obligated to provide Medicare with notice of all payments to Medicare beneficiaries, [**103] and (2) an injunction prohibiting the Escrow Agent from making disbursements to Medicare patients pending resolution of the Government's claims, and to compel disclosure of identifying information concerning all past or contemplated settlement payments to Medicare beneficiaries.

[*909] Although both declaratory relief and injunctive relief may be unnecessary depending on further developments on remand, the entire landscape of this case has changed with our disposition of this appeal. We prefer for the district court to evaluate the need for such relief in the first instance in light of the new landscape. [41] We therefore vacate the dismissal of the Government's claims for declaratory and injunctive relief, which will enable the district court to fashion the most appropriately tailored remedy. [42]

[**104] **VII. CONCLUSION**

We reverse the district court's dismissal of Counts I, II, III and IV as they regard the RSP Defendants. We also vacate the district court's dismissal of the Government's requests for declaratory and injunctive relief in Counts V and VII. Finally, we affirm the district court's dismissal

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[39] From the comments of counsel for the Government at oral argument, and from the parties' discussion at the hearing before the district court on May 15, 2000, we discern that the Government's main interest in laying a claim for reimbursement against the Escrow Agent was to keep the Agent in the case as a party so that he would be subject to any order granting appropriate injunctive relief. We note that Count VII, seeking injunctive relief against the Escrow Agent, is still alive, see Part III.B.(6), *infra*. Thus, pending further developments in the district court on remand, the Escrow Agent remains a party. In any event, we believe that the district court would retain the ability to direct the Escrow Agent's management of the settlement funds as required to preserve the Government's rights, whether or not substantive claims remain against him, either pursuant to the court's supervisory powers, or by retaining him or joining him to afford appropriate relief to the parties.

[40] The references to "a State agency" and "a private insurer" in § 411.24(g) indicate that HHS believes a party can be a recipient of payment even if all it is receiving is reimbursement for its own prior payments, rather than (as with a doctor) a fee for services rendered.

[41] For example, it is not beyond doubt that there may be need of injunctive relief to afford complete relief to the parties.

[42] We suspect that most of the Government's requests for injunctive relief will be effectively moot in any event. Because we reinstate the bulk of the Government's substantive claims for damages, discovery can now proceed and the Government will thereby gain access to the information it sought by way of a declaratory or injunctive order. In light of this likely mootness, we do not address the Defendants' arguments regarding whether, and to what extent, the MSP statute allows for declaratory or injunctive relief as a remedy.

of Count VI, which sought reimbursement from the Escrow Agent as an entity receiving payment. [43]

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

[43] As noted, the Government has abandoned Counts VIII and IX.

EXHIBIT C

ESSAY

ADMINISTRATION OF THE 2003 TOLBERT PCB SETTLEMENT IN ANNISTON, ALABAMA: AN ATTEMPTED COLLABORATIVE AND HOLISTIC REMEDY

Edgar C. Gentle, III[*]

ABSTRACT

The author was the court-appointed administrator of a $300 million dollar settlement between 18,000 claimants and Solutia, Inc., Monsanto Company, and Pharmacia Corporation (Tolbert Defendants),[1] *respecting polychlorinated biphenyls (PCBs) in Anniston, Alabama. In addition to paying for claimed personal injury and property damages, the settlement paid for a medical clinic, and sponsored scientific research and community reconciliation that have begun to provide a holistic remedy. Impediments to case administration were disparate payments to claimants in other settlements, liens on 30% of claimants, and claimant poverty. A collaborative model was used to design the settlement, to help ensure fairness, and to avoid a Rube Goldberg settlement matrix. Settlement design and distribution documents are found at www.tolbertqsf.com.*

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1. Of the Tolbert Defendants, Pharmacia Corporation is the successor of the Old Monsanto Corporation; with a mere name change, Solutia, Inc. was spun off by the Old Monsanto Corporation in 1997; and Monsanto Company was created in 2000.

[redacted]

INTRODUCTION

In 2001, a lawsuit was brought in federal district court before the Honorable U.W. Clemon against the Tolbert Defendants with respect to PCBs manufactured over a span of forty years in Anniston, Alabama.[2] Instead of a class action, the case consisted of an aggregation of 18,000 individual claimants, with 78% of the claimants born before June 30, 1985, and classified as adults, and the later born 22% of the claimants classified as children. The claimants live (or previously lived) in Anniston, Alabama, near a manufacturing plant that formerly produced PCBs—now owned by Solutia, Inc. but previously owned by Pharmacia Corporation—and claim to have suffered property damages and personal injury resulting from PCB exposure.[3] 90% of the claimants are African-American, and 80% earn less than 200% of the federal poverty level—the case resulted from the manufacture of PCBs in a poor, mostly black neighborhood. The case illustrates unforeseen consequences of the manufacture of useful but toxic substances, such as Agent Orange.[4]

The *Tolbert* case settled in September 2003 in tandem with the sister Alabama state court case, *Abernathy v. Monsanto Co.*[5] Each case settled

2. Oliver v. Monsanto Co., No. 2:02-CV-836-UWC (N.D. Ala. 2002); Tolbert v. Monsanto Co., No. 2:01-CV-1407-UWC (N.D. Ala. 2001).

3. PCBs were used in hundreds of popular commercial applications, including electrical transformers and capacitors, hydraulic equipment, and paints, and many other industrial products. PCBs were manufactured in Anniston from 1929 until 1971. The manufacture and sale of PCBs was subsequently prohibited by the Toxic Substances Control Act of 1976, 15 U.S.C. § 2605(e) (2000), due to PCBs' resistance to environmental breakdown and potential health concerns.

The effect of PCBs on human health remains greatly debated. However, it has been established that PCBs cause chloracne to the skin, and there is also evidence that PCBs tend to cause cancer in animals and impact animal immune, reproductive, and endocrine systems. *See* AGENCY FOR TOXIC SUBSTANCE & DISEASE REGISTRY, U.S. DEPT. OF HEALTH & HUMAN SERVS., PUBLIC HEALTH STATEMENT: POLYCHLORINATED BIPHENYLS 5 (2000), http://www.atsdr.cdc.gov/toxprofiles/tp17-c1-b.pdf [hereinafter PUBLIC HEALTH STATEMENT: POLYCHLORINATED BIPHENYLS].

4. As noted by Yale Professor, Peter H. Schuck: "In the Agent Orange case, we confront an unprecedented challenge to our legal system: a future in which the law must grapple with the chemical revolution and help us live comfortably with it." PETER H. SCHUCK, AGENT ORANGE ON TRIAL: MASS TOXIC DISASTERS IN THE COURTS 6 (1986).

5. No. CV-2001-832 (Ala. Cir. Ct. 2002).

for $300 million and both were approved at a joint fairness hearing, but *Tolbert* had five times as many claimants as *Abernathy*. Both cases were aggregate non-class settlements without a preceding class action.[6] Of the $300 million *Tolbert* settlement, $275 million was paid into a settlement fund, and the $25 million balance funded a claimant medical clinic. Appointed by the court as claims administrator at Thanksgiving 2003, the author's job has been to decide with the court and counsel for the plaintiffs how the *Tolbert* settlement fund should be distributed among the claimants and to administer the medical clinic. A sister federal case provided for property remediation in the impacted area.[7]

I. THE SETTLEMENT CLIMATE OF CONTROVERSY

Of the 18,000 claimants in the *Tolbert* case, about 14,000 lived in Alabama, mostly in the Anniston area, but 4,000 lived in forty-four other states and overseas. Two hundred were in prison and one hundred were located in foreign countries. Three hundred were deceased when *Tolbert* settled.

Figure 1 summarizes the financial status of the *Tolbert* settlement as we began to decide how to divide it among the claimants in the spring of 2004.[8] Of the $275 million in cash, $120 million had been paid in legal fees (40% of $300 million pursuant to written contracts between the claimants and plaintiffs' counsel),[9] and $9 million was used for the advance payment program under which claimants got $500 for providing accurate identification data. Conducting blood tests on the claimants for PCBs would cost about $4 million,[10] and this was one of the few administrative

6. Little previous scholarly attention has been given to such aggregate non-class settlements. *See* PRINCIPLES OF THE LAW OF AGGREGATE LITIGATION §§ 1.02, 3.01, 3.15 cmt. a (Proposed Final Draft 2009).

7. United States v. Pharmacia Corp., No. 02-C-749-E, 2003 WL 22319070, at *4–*8 (N.D. Ala. Aug. 4, 2003).

8. *See infra* fig. 1.

9. The size of the fee was controversial, with many claimants believing it was too large. If the case had been a class action, the fees might have been 25% to 50% less. Question: Is a large aggregate individual claimant settlement better treated as a class action when setting the level of fees? Professor Vairo asked, in connection with the Dalkon Shield settlement: "Are contingent fees ranging from twenty-four to fifty percent for settling Dalkon Shield claims appropriate if a claim is settled without the need for negotiation or formal dispute resolution" for each claim? Georgene M. Vairo, Essay, *The Dalkon Shield Claimants Trust: Paradigm Lost (or Found)?*, 61 FORDHAM L. REV. 617, 619–20 (1992).

10. In order to divide the personal injury monies among the claimants fairly, we had to determine their relative PCB levels. PCBs are found in the blood and the fat of humans. However, probably everybody has PCBs in their fat because PCBs are ubiquitous at this point. Two of our expert medical panelists, Dr. David Carpenter and Dr. Coreen Hamilton, advised us to conduct a PCB blood test, which would better distinguish PCB levels among claimants than a fat test, and which is about one-fourth as expensive as a fat test. PCBs come in 209 varieties, called congeners. Dr. Hamilton, a biochemist, suggested that we test for the ten PCB congeners that she indicated are the most frequently found around the plant in Anniston.

[redacted]

expenses the defendants did not agree to pay under the settlement. The defendants, however, did agree to pay virtually all other claimant payment administrative expenses, such as the author's administrative fees in processing and paying claims. This aspect of settlement design helped convince the claimants that we were committed to their case because we were not competing for the same pot of money.

After reserving for other administrative payments in Figure 1, there was about $142 million to pay claims, averaging about $7,800 per claimant. Figure 1 was mailed to the claimants to give them a realistic picture of expected payments due to high claimant expectations resulting from the *Abernathy* case, which paid its claimants five times as much. Adding to the disparity in payments among community members was the payment scale in the first PCB settlement of *Owens* in 2001[11] of $20,000 per claimant.

We began blood testing the claimants in January 2004 and completed our first round of testing in June 2005. 80% of the claimants were blood tested in Anniston, with the drawing and collection of blood being organized with LabCorp, and with blood testing being done by four separate laboratories: Northeast Analytical, AXYS, EnChem (now Pace), and Maxxam. We also organized with LabCorp blood-testing *sites* for claimants in or near the forty-four other states where they were located. Blood testing claimants overseas proved to be impracticable. A special prisoner blood test was conducted for the approximately two hundred claimants incarcerated in Alabama, but blood testing of out-of-state prisoners also proved to be unworkable.

Because we were not able to blood test all claimants, even if they were willing to be so tested, we implemented in the summer of 2005 an option under which claimants could elect to receive $288.50 in lieu of being blood tested, with this amount being the approximate cost of a blood test. In selecting this option, as described below, a claimant would waive a payment for the PCB blood test results, with adult claimants also waiving the right to payment for a registered nurse interview, but with children claimants not so waiving the right, due to the children's payment enhancement described below.

Settlement-fund-underwritten blood testing was completed for adults in July 2006 and for children in August 2007. Because many of the children are still under nineteen years old, with the last claimant reaching nineteen in 2021, the remaining approximately 350 untested children will still be allowed to be blood tested in the future at their own expense, as a compromise between honoring the legal rights of children as they become adults and helping the settlement fund plan its budget.

This has been the largest blood test in the history of litigation. For each claimant tested, the PCB results were determined on a parts-per-billion basis for each of the ten congeners tested, with the results for the ten congeners then being added to determine a total parts-per-billion score for each claimant. Because of anticipated lower PCB levels in children, a more sensitive test was used than for adults.

When we were engaged to administer the case, limited medical data had been collected for the claimants. Therefore, at the same time that we blood tested the claimants, they were interviewed by a registered nurse in order to obtain standardized medical data for each claimant. Alabama-tested claimants were interviewed onsite by a battery of registered nurses. Registered nurses telephoned out-of-state claimants and interviewed them on the telephone, and claimants that still had not provided the necessary registered nurse interview data were allowed to complete a yellow registered nurse interview form in lieu of an interview. The provision of registered nurses was organized with Medical Staffing Network.

The registered nurse interview form used is based upon input from the *Tolbert* medical panel on what diseases may or may not be caused by PCBs. We then developed a medical score scale of zero to one hundred with our medical panel to rank medical score results collected by the registered nurse interviews.

11. *See* Owens v. Monsanto Co., No. CV-96-J-0440-E (N.D. Ala. 2001) (involving 1,596 claimants receiving $20,676.69 each, or arguably much less per capita than *Abernathy* claimants re-

[redacted]

ceived). Ironically, the *Owens* claimants had unanimously approved their settlement but became seriously upset with the subsequent *Abernathy* settlement when it appeared that *Owens* claimants had not received the same amount per capita. Plaintiffs' counsel in the *Owens* case subsequently filed an October 28, 2003 motion to enforce the settlement agreement, based on the following Most-Favored-Nation Clause in the *Owens* April 16, 2001 settlement agreement with the defendants:

> In the event Monsanto/Solutia enter into a settlement agreement after the date of this Agreement in another multi-plaintiff PCB/Anniston plant-related lawsuit that is subject to this paragraph and that results in a net present value of the per capita gross cash recovery that exceeds $20,676.69, then Monsanto/Solutia shall make such additional payments under the terms of this paragraph as may be necessary to make the net present value of the per capita gross cash recovery in this lawsuit equal to the net present value of the per capita gross cash recovery in such other settlement.

Settlement Agreement at 15, Owens v. Monsanto Co., No. CV-96-J-0440-E (N.D. Ala. 2001) (on file with author).

In a December 3, 2003 response, the defendants took issue with the suggested math in the *Owens* plaintiffs' motion, suggesting that, first, because *Tolbert* and *Abernathy* were part of a global PCB settlement, a combined $600 million is the gross amount of the numerator involved, instead of the $300 million in *Abernathy*, and the denominator involved 21,000 plaintiffs in *Tolbert* and *Abernathy* combined instead of the 3,500 in *Abernathy* alone. The defendants further argued for four numerator reduction adjustments: (i) $15 million in costs paid by the defendants; (ii) $25 million for the medical clinic; (iii) $60 million in individual grants to some but not all plaintiffs in the *Abernathy* action through a foundation, trust or other organization; and (iv) a $150 million property relocation/adjustment fund paid to a subset of the *Abernathy* population, reducing the numerator from $600 million to $350 million. Hence, under the defendants' math, the per capita amount under the global PCB settlement agreement, involving *Tolbert* and *Abernathy* plaintiffs, was $16,667 ($350 million/21,000), or less than the per capita payment in *Owens*.

By order dated January 8, 2004, the Honorable Inge P. Johnson, who presided over the *Owens* Case, decided that only the *Abernathy* Case should be considered for purposes of the *Owens* Most-Favored-Nation Clause computation, without its being cumulated with the *Tolbert* Case. After subtracting (i) $150 million for a property/relocation fund; (ii) $60 million for a foundation fund; and (iii) $15 million for costs, Judge Johnson found a net amount for the *Abernathy* claimants of $75 million, which, when divided by the 3,466 *Abernathy* plaintiffs, equals $21,514.63 per capita or $837.94 more than the *Owens* plaintiffs received, for a net due the *Owens* settlement of $1,337,352.20.

This order was appealed to the Eleventh Circuit Court of Appeals. The Eleventh Circuit affirmed the federal district court by orders dated August 19, 2004; November 8, 2004; and January 5, 2006. Plaintiffs' counsel in the *Owens* Case then petitioned the United States Supreme Court for certiorari on November 2, 2007, and the petition was denied on January 7, 2008.

[redacted]

TOLBERT, ET AL. V. MONSANTO CO., ET AL.
AMOUNT AVAILABLE TO PAY CLAIMS
AT DECEMBER 31, 2003

Settlement Amount
$ 300,000,000

Tolbert Qualified Settlement Fund
$ 275,000,000

Medical Clinic: $ 25,000,000 In Ten Yearly Installments of $2.5m plus $500,000 from Pfizer plus $2.0 million from Pfizer plus $100,000 from Science Study license of PCB Blood Test Data, for total of $27,600,000

Beginning Balance		$275,000,000
Plaintiffs' Attorney Payments	-	$120,000,000
Advance Payments (Adults)	-	$7,000,000*
Advance Payments (Children)	-	$2,000,000*
PCB Blood Test Budget	-	$3,985,000*
2003 Estimated Income Tax Payment	-	$150,000
2003 Income	+	$668,161
Amount Available to Pay Claims		$142,533,161 *
Average Amount Available Per Claimant Following Advance Payment (18,447 claimants*)		$ 7,726.63*

*Numbers are Estimates

Figure 1: Summary of financial status of *Tolbert* settlement as of December 31, 2003

[redacted]

A fourth PCB case, *Clopton v. Monsanto Co.*, was filed for 5,000 to 7,000 PCB claimants in the same federal court in 2003.[12] In *Clopton*, the court denied requested class certification because "questions of law or fact common to class members" did not "predominate over any questions affecting only individual members."[13] Hence, a global PCB class action settlement may not have been available in *Tolbert* and *Abernathy*, absent agreement. These four "bites at the PCB apple" illustrate the potentially unfair results of the piecemeal settling of toxic tort cases. The four cases included 28,000 to 30,000 individuals, and considering that Anniston's population in the year 2000 was 21,000, and Calhoun County, Alabama, where Anniston is situated, had a population of 113,000 in the year 2006, the impact of the PCB litigation on this Alabama community has been pervasive.

In retrospect, the fairest solution for the Anniston PCB contamination problem may have been a one-time global class action settlement. However, the class action solution to mass tort settlements has come increasingly under fire, and the court's decision not to class the *Clopton* case casts doubt on the availability of this solution.[14]

Other attempted or suggested solutions to curb huge discrepancies in awards among similarly situated mass tort plaintiffs include a comprehensive national medical disability system, or national legislation, such as that passed to compensate 9/11 victims and nuclear reactor victims for personal injury.[15] Even with such global solutions, the debate on a fair compensation rate continues.[16]

An example of the resulting climate of controversy experienced in the Anniston community over these multiple and disparate PCB settlements is

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12. Clopton v. Monsanto Co., No. CV-03-UWC-3369-S (N.D. Ala. 2003).
13. FED. R. CIV. P. 23(b)(3).
14. *See* Kenneth R. Feinberg, *Reporting from the Front Line—One Mediator's Experience with Mass Torts*, 31 LOY. L.A. L. REV. 359, 361 (1998) (championing the Rule 23 solution to mass tort settlements); *In re* Joint E. & S. Dists. Asbestos Litig., 120 B.R. 648, 656 (E.D.N.Y. 1990) (Johns-Manville Asbestos Trust implementing this remedy); *In re* Agent Orange Prod. Liab. Litig., 597 F. Supp. 740, 839 (E.D.N.Y. 1984) (Agent Orange settlement implementing this remedy). Compare, however, more recent cases strictly applying Rule 23 to reject class action settlements. *See* Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 613–29 (1997); Castano v. Am. Tobacco Co., 84 F.3d 734, 740–52 (5th Cir. 1996); *In re* Rhone-Paulenc Rorer, Inc., 51 F.3d 1293, 1297–1304 (7th Cir. 1995).

Arguably, in reviewing the Asbestos proposed settlement of the *Tolbert* case, Judge Clemon's hands were tied because of the accepted rule that a court must approve or disapprove a settlement as a whole and cannot materially change it by, for example, putting all the *Abernathy* and *Tolbert* money in one bucket and dividing it ratably among all the claimants from both the cases. *See* Bowling v. Pfizer, Inc, 143 F.R.D. 141, 150–51 (S.D. Ohio 1992). *See generally In re* Agent Orange Prod. Liab. Litig., 597 F. Supp. 740 (E.D.N.Y. 1984); Cox v. Shell Oil Co., No. 18844, 1995 WL 775363 (Tenn. Ch. Nov. 17, 1995).

15. *See* JACK B. WEINSTEIN, INDIVIDUAL JUSTICE IN MASS TORT LITIGATION 155–59 (1995). *See also* SCHUCK, *supra* note 4. *See generally* 42 U.S.C. § 2210 (2006); Kenneth R. Feinberg, Lecture, 56 ALA. L. REV. 343 (2004) [hereinafter Feinberg Lecture].
16. *See* Feinberg Lecture, *supra* note 15, at 348–49.

[redacted]

found in a *Forbes* article where *Tolbert* claimant Rose Munford laments, "I'd like for someone to explain to me how this makes sense."[17]

To help explain to our claimants why plaintiffs' counsel settled *Tolbert* for much less per claimant than *Abernathy*, Bob Roden, the *Tolbert* plaintiffs' liaison counsel appointed by Judge Clemon, sent the claimants the letter in Figure 2.[18] As the Roden letter relates, the *Tolbert* case was a relatively young one at the time of settlement, having been filed only a couple of years before it settled.[19] By contrast, *Abernathy* had been litigated for seven to eight years, and many of the *Abernathy* claimants already had favorable jury verdicts.[20] In addition, one of the defendants in the *Tolbert* case, Solutia, had threatened bankruptcy.[21] In settlement discussions, the defendants argued that if the *Tolbert* claimants' lawyers did not accept the $300 million offer, the claimants may receive nothing, with Solutia threatening to go into Chapter 11 bankruptcy, and staying the case, perhaps indefinitely.[22] If this had happened, the *Tolbert* claimants would have had to file bankruptcy claims and might never have been paid anything. Indeed, after the *Tolbert* case settled, Solutia filed a petition in bankruptcy in December 2003 as a Chapter 11 debtor.[23]

II. CLAIMANT PAYMENT PROGRAM DESIGN BY COLLABORATION

Because of the financial and social challenges in our case, and to be as fair to the claimants as possible, we designed our settlement with a maximum amount of claimant input, including large town meetings where we answered every question raised, convening a claimants advisory committee, mailing the claimants a questionnaire on claimant payment program design based upon the town meetings and input from the claimants advisory committee, drafting a resulting payment matrix and mailing it to the claimants for further input, and having three days of fairness hearings at which the claimants could be heard on design of the payment program.

Wearing the "creative problem solver" hat of a claims administrator described by Kenneth Feinberg,[24] we tried to sell the settlement to the community and crafted its payment design through attempted consensus. The fairness hearing may have served as an imperfect surrogate for the traditional aggregate non-class settlement ethical rule that claimants must approve the settlement before plaintiffs' counsel may do so, which did not

17. Susan Kitchens, *Money Grab*, FORBES, Nov. 15, 2004, at 162, 168.
18. Letter from Robert B. Roden, *Tolbert* Plaintiff's Liaison Counsel, to *Tolbert* Claimants (March 18, 2004). The letter is reprinted *infra* figure 2.
19. *Id.*
20. *Id.*
21. *Id.*
22. *Id.*
23. *Id.*
24. Feinberg, *supra* note 14, at 361.

[redacted]

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March 18, 2004

Dear Claimant:

Many of you have questioned the decision to settle the Tolbert/Oliver case for 300 million dollars, when the Abernathy claimants were receiving the same amount. Many factors played into this including:

1). The fact that the Abernathy plaintiffs had been in litigation for seven to eight years.

2) That actual verdicts were being handed down in the Abernathy case (a jury had actually been impaneled for 18 months).

3) Abernathy had twice been argued before the Alabama Supreme Court.

4) On average the Abernathy plaintiffs lived closer to the Solutia/Monsanto facility.

The attorneys for the Tolbert plaintiffs argued long and hard that all these factors should be given less weight and that Tolbert plaintiffs should receive more.

In the end the attorneys for Tolbert were advised that 300 million was all there was for them; and further that if it were not accepted Solutia was prepared to file for bankruptcy within a few days. This raised the real possibility that the plaintiffs could get little or nothing.

The attorneys for the plaintiffs researched the bankruptcy issue and hired outside counsel specializing in bankruptcy. In the end, it was their conclusion that the plaintiffs were at risk of receiving nothing if Solutia did bankrupt. As you all know, Solutia did subsequently file for bankruptcy. We should all be thankful that the case had already settled and the settlement will not be affected by this unfortunate event.

The attorneys in the Tolbert matter worked very long and hard for the plaintiffs and used their best judgment in the end. We all appreciate the tragedies you people have suffered and we all continue to be with you. Thank you for allowing us to represent you in this matter. We look forward to seeing you all at the next community meeting.

Very truly yours,

Robert B. Roden

Robert B. Roden

Figure 2: Plaintiffs' counsel letter to *Tolbert* claimants

[redacted]

happen here.[25] Following the fairness hearing, we made our final recommendations to the court on payment program design, which were approved in June 2004. Claimant personal injury payments began immediately, with the first batch of checks going out two days later on June 16, 2004, and with the oldest claimants being paid first. We are unaware of any other mass tort payment program so designed through attempted claimant consensus. This method carried out Judge Jack B. Weinstein's advice in mass tort settlements to let the claimants tell their stories in distribution plan design so that they will believe that the resulting plan is more just, and to allow the neutral special master to experience the necessary empathy element of fair decision making.[26] At bottom, though, this settlement plan, like many others, was arguably ad hoc private tort reform without legislative safeguards.[27]

Defining fairness, much as Mr. Feinberg does, as consistency,[28] the settlement payment matrix had no subjective factors. Applying our democracy theme, the claimants' answers to the questionnaire and the fairness hearing were the major factors in plan design.

The first design step was to split the settlement fund between personal injury and property damage. The vast majority of claimants agreed that personal injury was more important. We therefore came up with a simple proposal that personal injury would count twice as much as property damage, so that, with 18,500 claimants and 3,000 parcels, a 93/7 split was computed.

The resulting $11 million property damage fund was distributed to the claimants in proportion to the tax appraised value of their property in the affected area because we did not have the resources to test the property for PCBs and PCB levels varied greatly due to flooding over the years, contamination of the soil by neighboring foundries, and relocation of fill dirt. Similar property payment programs have been used in other toxic tort settlements.[29]

The property damages program was the easy part of the payment matrix, with the difficulty coming with personal injury, as subjective factors

25. *See* ABA Comm. on Ethics and Prof'l Responsibility, Formal Op. 06-438 (2006). *But see* PRINCIPLES OF THE LAW OF AGGREGATE LITIGATION § 3.17 cmt. b (Proposed Final Draft 2009) (suggesting the aggregate settlement rule should be relaxed for large-scale settlements, such as *Tolbert*). See also Adam Liptak, *In Vioxx Settlement, Testing a Legal Ideal: A Lawyer's Loyalty*, N.Y. TIMES, Jan. 22, 2008, at A12, for a discussion of the recent aggregate non-class $4.85 billion global Vioxx settlement, where the participant plaintiffs' counsel were required to settle for all of the plaintiffs with no opt-outs, much as in *Tolbert*, with the amount due each plaintiff to be determined later, much as in *Tolbert*.

26. WEINSTEIN, *supra* note 15, at 8, 10, 13, 56–59, 161.

27. *See* JAY TIDMARSH, MASS TORT SETTLEMENT CLASS ACTIONS: FIVE CASE STUDIES 6 (1998), http://www.fjc.gov/public/pdf.nsf/lookup/Tidmarsh.pdf/$file/Tidmarsh.pdf.

28. Feinberg Lecture, *supra* note 15, at 553.

29. September 2004 Settlement Approval Order in *Samples v. Conagra* and *Williams v. Conagra*, in the State Circuit Court of Pensacola, Florida.

[redacted]

are almost impossible to eliminate. In designing the personal injury program, we first had to divide the corpus between the 78% who were adults and the 22% who were children represented by a guardian *ad litem*. Because the children could not be paid until age nineteen, and the last child would not reach that age until 2021, the money would be held for them for a longer time. In the meantime, the adults wanted to be paid immediately, with their friends and relatives in the *Abernathy* case already having been paid in the spring of 2004. An initial proposal to divide the money based upon the number of claimants in the two categories was abandoned because detectible PCBs from the blood test were found three times more frequently in adults than children and adult PCB levels averaged eight times as high as for children. After considerable thought and claimant input, the court decided to pay adults and children at the same rate for PCB levels, with $8 million therefore being available for children and $123 million being available for adults, with some enhancements for children as described below. Children payments bear an interest component.

Directly linking PCBs with personal injury was very difficult, with the defendants conceding only that they cause chloracne.[30] Therefore, we focused on three objective, relatively easily proven criteria for personal injury: the claimant's score on the PCB blood test, the claimant's score of zero to one hundred based upon a registered nurse health interview designed with input from our medical panel, and the number of years the claimant lived in the impacted area. Because this is a PCB case, after hearing all the claimants and reviewing the questionnaire results, the court decided to give PCB levels the greatest weight, with the three factors being scored 70/15/15. However, adults scored zero on the registered nurse interview if they did not have detectible PCBs because such a claimant would not be able to show linkage between PCBs and disease had his case gone to trial.

82% of the claimants answering the questionnaire thought they should be paid for living in the impacted area even if they scored negative on the PCB blood test and were not sick, apparently because this factor attempts to measure the time of exposure that a claimant experienced over time in

30. As pointed out by Professor Schuck:

> In the toxic tort dispute, the nature of the injury is very different and the processes of establishing, defining, and measuring that injury are far more complex. A chemical agent . . . is suspected of having harmed one or more individuals. Often the pathways of causation are difficult to detect, the time periods extend over decades, and the effects are not readily isolated or scientifically understood.

SCHUCK, *supra* note 4, at 8–9. Other judges have struggled with the traditional tort requirement for provable personal injury in order to justify a mass tort recovery. For example, the Supreme Court rejected recovery for emotional distress in connection with asbestos inhalation in *Metro-N. Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 432–37 (1997). *Cf.* Keene Corp. v. Ins. Co. of N. Am., 667 F.2d 1034, 1041–42 (D.C. Cir. 1981); Uniroyal, Inc. v. The Home Ins. Co., 707 F. Supp. 1368, 1394 (E.D.N.Y. 1988).

living near the plant. The court agreed, thereby assuring that almost all the claimants received a payment, however small. This helped make peace among the claimant population, with communicatarian or feminist justice for the group as a whole taking precedence over individual justice for the claimants most contaminated with PCBs, much as happened in designing the Dalkon Shield and Agent Orange settlements.[31]

Because the personal injury fund was split between children and adults based on their PCB levels, the children stood to receive very little money unless their payments were enhanced. The court decided to award children without detectible PCBs 50% of their registered nurse interview score, even though a similar adult would receive zero, and the child with a PCB contaminated mother 100% of the nurse score, under the theory that the children may have been contaminated with PCBs in the placenta, but with PCBs now being diluted and non-detectible. In addition, children only had to live in the impacted area five years instead of the ten years required of adults to receive a payment because of the more acute impact that PCBs are thought by some experts to have on children than adults.[32] Due to the tremendous pressure to pay *Tolbert* claimants, as the sister *Abernathy* case had already been paid, and due to our claimants' great poverty, we could not wait until all of the claimants were blood tested and all of the payments were computed to pay them.[33] Instead, we began to pay the claimants right after the payment program was approved in June 2004 based upon an estimate, with a 20% reserve.[34] This was followed by a second dividend in the summer of 2005, and a final dividend in December 2005, when almost all of the claimants had been scored for personal injury. The average adult personal injury payment was $9,100, including the $500 advance payment, with the average child claimant receiving $2,000.

31. *See* SCHUCK, *supra* note 4, at 12, 295–96; WEINSTEIN, *supra* note 15, at 170; Vairo, *supra* note 9, at 619, 621–23.

With the Court having established that 70% of personal injury payments would be based upon PCB levels, we faced a dilemma with 300 deceased claimants who had not been blood tested for PCBs. Discussion with the claimants advisory committee revealed that families of these claimants would be satisfied if they received about $4,000, with the family understanding that a blood test was impossible. Noting that, based upon the average date of death of a deceased claimant, the claimant was likely to have had PCBs, the court decided to pay the families of deceased claimants based upon the registered nurse interview score and the years of living in the area of concern, as if they had a positive PCB score, with the resulting payment averaging $5,500. Under this approach, the families were satisfied.

32. PUBLIC HEALTH STATEMENT: POLYCHLORINATED BIPHENYLS, *supra* note 3, at 6.

33. Historically, trustees and special masters administering mass torts risk termination if they do not move with alacrity. This happened to three of the five trustees in the Dalkon Shield settlement. *See In re* A.H. Robins Co., 880 F.2d 779, 788 (4th Cir. 1989); Vairo, *supra* note 9 at 632–33.

34. Judge Weinstein recommends internal administrative appeals to the special master in designing mass tort settlements. *See* WEINSTEIN, *supra* note 15, at 143–48.

III. Fielding Appeals, Taming the Sea of Liens, and Simplifying Taxes

As a condition to fairness, the payment program allowed dissatisfied claimants to appeal the computation of their personal injury or property payments.[35] Indeed, Professor Feinberg created an appeals process in administering the 9/11 claimant payment statute even though it is not provided for.[36] A retired circuit judge was appointed as the appeals special master. Of the 18,000 property damage and personal injury claims paid to date, 970, or 5%, were appealed. Although this rate is five times that experienced in MDL 926, the breast implant settlement, all but a handful of claimants seem satisfied with the *Tolbert* appeals process and none are pending.[37]

Unlike the 9/11 settlement where liens were self-reported by the claimant or the MDL 926 settlement where a small number of liens were filed with the claims office,[38] in the *Tolbert* case, 30% of the claimants had liens or potential liens against their claims due to prior bankruptcies; child support judgments; civil judgments; restitution; and medical liens of the Veterans Administration, Social Security, Medicare or Medicaid. For example, there were $5 million of child support judgments against the claimants alone.

For each category of lien, we tailored a lien resolution process that facilitated a potentially reasonable settlement with the lienholder but reserved the claimant's right to contest the lien. For example, the 20% of claimants with Medicare liens could pay Medicare 10% of their personal injury payment or contest the lien, and claimants with bankruptcy liens could split their personal injury payment with the bankruptcy estate under a sliding scale determined by how long ago the claimant filed for bankruptcy. For restitution and child support liens, the claimant could either agree to the lien or participate in an interpleader action to contest it.

To clarify the income tax consequences of each payment received by a claimant, the payments were divided into personal injury, which is not taxable,[39] and property, which potentially is.[40] The checks were different colors, and each check came with an explanatory sheet on the tax conse-

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35. Feinberg Lecture, *supra* note 15, at 547.
36. *Id.* at 547. As escrow agent for MDL 926, I paid all the personal injury claims—perhaps 5% involved lienholders.
37. E-mail from MDL 926 Claims Administrator, to Edward C. Gentle, III (July 22, 2009, 14:39:45 CST) (on file with author).
38. As this was not a class action, the eighty-eight claimants providing special services to plaintiffs' counsel in developing the *Tolbert* case could not be paid as lead plaintiffs. Nevertheless, the majority of claimants agreed in their questionnaires that these claimants should be paid for developing the case, with the average claimant receiving $13,000.
39. 26 U.S.C. § 104(a)(2) (2000).
40. 26 U.S.C. § 61(a) (2000).

quences of the payments. Unlike the *Abernathy* case, where the claimants received a combined personal injury and property payment, the number of Internal Revenue Service inquiries of our claimants has been small and they appear to have been resolved.[41]

IV. Crafting a Holistic Remedy to Cure the Long-Term Health Dilemma and Begin to Reconcile the Community

Concerned about the unknown long-term health effects of PCBs, we asked the claimants in our questionnaire if some of the personal injury money should be held in reserve for claimants that get sicker later. 95% of the claimants rejected this proposal, bearing out Mr. Feinberg's prediction that, when presented the opportunity to accept money now, claimants do so, because they are future-risk averse.[42] Fortunately, the parties and the court already included a long-term care provision in the *Tolbert* settlement: the $25 million earmarked for a medical clinic.

To make economical use of this grant, two incumbent Anniston clinics are used, one for adults and one for children, instead of building one from scratch. 4,000 adults and 1,000 children claimants make use of the clinic, which provides approximately 2,000 pharmaceutical prescriptions per month and primary medical and dental care.[43] In order to take full advantage of third party payments available from private insurance and government, and to maximize the value of clinic resources, a "retail model" is used with a third party administrator for medical care and a pharmacy benefit manager for the twenty pharmacies in the area that provide prescriptions. Prescription co-pays and annual medical and prescription benefit caps further conserve resources. We project that the clinic endowment will last about fifteen years, thanks to these frugal measures. Although the clinic project was unpopular with the claimants at first because they wanted all of their cash up front, it is now perceived as providing a dynamic remedy compared to the *Abernathy* and *Owens* cases.[44]

A clinic long-term planner, whose salary is paid by plaintiffs' counsel and the author, organizes scientific research and obtains clinic grants. Because of the regrettable history of scientific research in Tuskegee, Alabama, and the mistrust associated with PCB contamination, implementing scientific research has been difficult. In order to facilitate community trust, a research committee, comprised of claimants and other residents,

41. *See* Abernathy v. Monsanto Co., No. CV-2001-832 (Ala. Cir. Ct. 2002).
42. Feinberg, *supra* note 14, at 368–69.
43. Quarterly Clinic Meeting Minutes (Feb. 18, 2009) (on file with author).
44. 95.3% of the 2,408 claimants responding to our March 2004 settlement design survey wanted to receive all their money now. Summary of Survey Results on Website (Apr. 21, 2004).

has created a code of conduct requiring potential researchers to disclose the methodology, goals, and uses of the scientific research.

Although members of other large mass tort settlements have grown to believe they are a community,[45] PCB contamination impacted a specific geographical community from the start. PCBs have resulted not only in property damage and personal injury, but have exacerbated division between races, economic classes, and communities in the area. Through additional funding obtained by the long-term planner from the Andrus Family Fund in New York, a reconciliation program was designed to nurture societal forgiveness, recovery, and growth. Focusing on children, who may be best able to forgive, the project enhances children's access to social, developmental, and educational resources for personal achievement. Hopefully, this reconciliation process will allow claimants to "let go" of their victim identity, and allow the community to recover and prosper.

Although settlement administration arguably loses its inherent judicial nature when venturing into community rebuilding, it is submitted that a community remedy is needed for a geographically discrete toxic tort.[46]

V. SOLVING THE COMMUNICATIONS, OVERHEAD, AND SURPLUS PROBLEMS

Personal contact with claimants and ongoing communication—through meetings, a telephone bank, periodic update letters, and hearings—are key components in designing and administering a mass tort settlement.[47] As a result of the controversy concerning the *Tolbert* settlement and the poverty of the claimants, we received 200,000 claimant phone calls, about twelve per claimant. By contrast, in the MDL 926 breast implant case, we received 50,000 calls from 260,000 claimants, or one call per five claimants. In the Agent Orange case, over 500,000 calls were received[48] from 2.4 million Vietnam veterans and their families.[49] We also received about 200 letters from the claimants per week for the first two years, answering every one with a personal response as suggested by Judge Weinstein.[50] We made hundreds of emergency advance payments to adult claimants, met with claimant groups numerous times, and tried our best to explain this settlement to the claimants fully and to address all of their needs to the fullest extent possible.

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45. *See* WEINSTEIN, *supra* note 15, at 46–52 (discussing the community aspect that revolves around mass tort litigation); Vairo, *supra* note 9, at 623 (same).
46. Judge Weinstein agrees that in the mass tort context, communication relief—advancing the entire impacted community—is a necessary component. WEINSTEIN, *supra* note 15, at 46–52.
47. *See* Vairo, *supra* note 9, at 640–41. *See also* WEINSTEIN, *supra* note 15, at 12, 54–60.
48. *See* WEINSTEIN, *supra* note 15, at 12.
49. *See* SCHUCK, *supra* note 4, at 4.
50. *See* WEINSTEIN, *supra* note 15, at 54–55.

[redacted]

This collaborative, intensive-contact approach in claimant design and payment, and the average low amount per check of $2,100, put a strain on administrative expenses. Based upon our administrative experience in other settlements, we suggested a 5%-of-claims paid cap, and the defendants agreed. To carry out this plan, we had to write off 23% of our time, or $2 million. The resulting overhead per claim of $400 equals that experienced over a decade earlier in Dalkon Shield.[51]

Since the claimants were paid based on an estimate, using a statistical sample and requiring a reserve, there remains a $2.7 million surplus, or 1.8% of the $151 million originally available to pay claims. Due to claimant liens and the extremely small size of the resulting checks, we estimated that the overhead costs for issuing this surplus to the claimants would be 10%. As a result, the claimants advisory committee and the court agreed to use the surplus to endow the medical clinic further. Many claimants, however, remain dissatisfied with this result.

CONCLUSION

We attempted to design a collaborative settlement that is both forward-looking and holistic. The major factor in claimant payment design was claimant input. Instead of merely paying the claimants a check for claimed damages, the court implemented an EPA-supervised environmental clean-up, a medical clinic, and a reconciliation program to begin to heal the underlying scars from PCBs, discrimination, and poverty. Scientific research may help answer the rhetorical question of what PCBs do to human health.

It is the author's hope that the long-term legacy of this settlement will be an Anniston community that not only has begun to cure itself but is organized and united in facing what the future may bring.

51. *See* Vairo, *supra* note 9, at 654.

EXHIBIT D

March 12, 2020

CURRICULUM VITA

Name of Attorney:	Edgar C. Gentle, III, Esq.
Name of Firm:	Gentle, Turner, Sexton & Harbison, LLC
Profession:	Attorney
Date of Birth:	February 17, 1953
Years with Firm:	28
Nationality:	U.S.A.
Memberships in Professional Societies:	Admitted to Alabama State Bar (1981) and various Federal District Court and Appellate Court Bars

A. Key Qualifications

Ed Gentle was born in Birmingham, Alabama, February 17, 1953. He graduated summa cum laude in 1975 from Auburn University where he was a Danforth Scholar and earned a Bachelor of Science degree. In 1977 he received a Master of Science (summa cum laude) from the University of Miami as a Maytag Fellow where he became familiar with the law of the sea and international resource planning issues involving competing nations.

He was a Rhodes Scholar (Auburn's second and Miami's first) at Oxford University—where he earned a B.A. degree with honors in Jurisprudence in 1979 and a M.A. degree in 1980. He then attended the University of Alabama School of Law as a Hugo Black Scholar. He earned his J.D. and was admitted to the Alabama State Bar in 1981.

Mr. Gentle has comprehensive experience in serving as Special Master and Claims Administrator in Mass Tort Litigation, and providing grid design, claims administration and financial and business advice to Courts, Settling Parties, and Mass Tort Settlements. Approximately 90% of his professional time is devoted to this practice. He has helped create and administer over $2 Billion in Settlements during the past 25 years. He has also provided affidavit, deposition and hearing testimony on the fairness of Mass Tort Settlements.

From 1992 to 2014, Mr. Gentle served as Special Master and Escrow Agent for the MDL 926 Global Breast Implant Settlement, paying $1.2 Billion in claims for 300,000 claimants. From 2001 until 2003, he was Interim Financial Advisor for the Settlement Facility - Dow Corning Trust

(the Dow Corning Breast Implant Settlement) overseeing the investment of over $1 Billion and providing tax and accounting support for the Settlement, during part of Dow Corning's Chapter 11 Bankruptcy.

Commencing in December 2003, Mr. Gentle was appointed as the Settlement Administrator in the $300 Million Anniston, Alabama Tolbert PCB Settlement with Monsanto and Solutia in connection with the administration of a Global Settlement before the Federal District Court for the Northern District of Alabama applicable to 18,000 claimants with respect to PCB contamination of property and PCB personal injury claims. In administering the $300 Million settlement, Mr. Gentle designed the claimant payment program for property damage and personal injury, collected criteria for payments to each of the 18,000 claimants, ranked the claimants for payment amounts, satisfied private and government liens, and remitted payments to each of the claimants. The Settlement also provided primary medical and dental care and prescriptions to claimants, with this portion of the settlement being completed in 2016.

One of Mr. Gentle's specialties is serving as Settlement Administrator for Community Tort Settlements, such as a C-8 groundwater contamination case in Camden, New Jersey (with water filtration and damages 2004-2008), Warehouse Fire Settlements in Conyers, Georgia (2012) and Louisville, Kentucky (personal injury and property claims), Zinc Smelter Settlements in Spelter, West Virginia (medical monitoring and property remediation 2011-2017) and Blackwell, Oklahoma (property remediation 2013-2019), a coal slurry groundwater contamination Settlement in Mingo County, West Virginia (medical monitoring 2013), and two train wrecks in Kentucky (2010 and 2017), one in Alabama and one in West Virginia (personal injury and property claims 2017-2019).

In November, 2009, Mr. Gentle was appointed Claims Administrator in the Jefferson County, Alabama, Occupation Tax Refund Class Settlement before the Honorable David Rains, in the Circuit Court of Jefferson County. On May 14, 2010, the Supreme Court of Alabama upheld the $37 Million Judgment. The Parties entered into a Class Settlement, which was approved by the Court, and tax refunds were issued to over 300,000 claimants. The case was completed in 2014.

In June 2010, Mr. Gentle was appointed Special Master and Settlement Administrator in the Total Body Multi-district Litigation, MDL 1985. The claimed toxigen was a selenium overdose in a health maintenance drink, with claimed damages being hair loss and damage to bodily organs. Working closely with the Court, Mr. Gentle facilitated the aggregate settlement of all cases, in August 2010. Mr. Gentle and his staff determined the value of each of the settled cases, which was consented to by all Plaintiffs, and Mr. Gentle administered the Settlement, satisfied private and government liens, and paid all claimants, which was completed in 2013.

In the Fall of 2011, Mr. Gentle was appointed Claim Administrator for the 1,000 family Perrine v. DuPont Zinc Smelter Class Action Settlement in Spelter, West Virginia, involving a $40 million remediation program for soil and houses with respect to cadmium, arsenic, zinc and lead, and a 30 year medical monitoring program. The remediation program was completed in 2017, and the medical monitoring program will be completed in 2041.

In 2012, Mr. Gentle was appointed Claims Administrator of the Swiger v. AmeriGas, West Virginia statewide Class Settlement, involving monetary awards and remediation for approximately 12,000 claimants and with respect to propane gas lines.

Mr. Gentle is Special Master in the national MDL Blue Cross Antitrust Litigation, MDL 2406, with putative provider and subscriber classes, before the Honorable R. David Proctor, having been appointed in 2012. The case has 3 groups of litigants: the Policy Subscribers, the Medical Providers and the 37 Blue Cross companies. There are over 100 million potential plaintiffs. Among his duties are mediating a Settlement of the subscribers/Blue Cross litigation, and auditing subscriber and provider common benefit attorney time and expenses.

From 2012 to 2014, Mr. Gentle, as Special Master, facilitated the creation and administration of a 93 claimant settlement with an undisclosed manufacturer and hospital concerning CT-Scan radiation exposure, with claimed damages being hair loss and cognitive deficiencies.

In 2013 and 2014, Mr. Gentle administered four separate Pfizer Chantix Aggregate Settlements, designing the payment matrix, handling claimant appeals, resolving liens, and paying claimants.

In 2014, Mr. Gentle was appointed Claims Administrator for the Mingo County, West Virginia medical monitoring program, lasting 30 years and involving 750 claimants exposed to coal slurry well contamination. The program will be completed in 2044.

In 2013, Mr. Gentle was appointed Claims Administrator for the Coffey v. Phelps Dodge Oklahoma Circuit Court Class Settlement in Blackwell, Oklahoma with respect to a zinc smelter and involving a $34 million remediation project for 1,000 households with respect to cadmium, arsenic, zinc and lead. The program was completed in 2019.

In 2014, Mr. Gentle was appointed Plaintiff Lien Administrator for the Hydroxycut Mass Settlement.

In November 2014, Mr. Gentle was appointed Special Master in the Stryker Hip MDL, MDL 2441, handling settlement appeals and opt-out mediations.

In 2015, 2016, and 2017, Mr. Gentle was hired by Smith & Nephew and Plaintiffs' Counsel to facilitate three Memphis, Tennessee aggregate settlements involving artificial hips and to resolve related plaintiff liens.

In May 2016, Mr. Gentle was appointed Claims Administrator by the Escambia County, Florida, Circuit Court in Allen v. A.E. New, the Pensacola jail fire and explosion case, to facilitate the class settlement of the 667 claimant case. The Settlement was approved in 2018.

In October 2016, Mr. Gentle was appointed Special Master by the Fulton County, Georgia Circuit Court in Smart v. Brenntag, to carry out the administration of a chemical spill class settlement.

In February 2017, Mr. Gentle was appointed Settlement Administrator of an industrial plant contamination settlement in Bowling Green, Kentucky involving personal injury and property damages plaintiffs and Federal Mogul, with the Aggregate Settlement being approved by the Court in August 2018.

In September 2017, Mr. Gentle was appointed Claims Administrator for a GE factory fire class settlement in Louisville, Kentucky.

In October 2017, Mr. Gentle was appointed Special Master by the West Virginia Federal District Court for the Southern District of West Virginia to administer the Mt. Carbon 400 claimant aggregate train derailment settlement with Sperry (personal injury and property damage). Subsequently, in March 2018, Mr. Gentle was appointed Special Master to administer the portion of the Settlement applicable to CSX.

In October 2017, Mr. Gentle was appointed Escrow Agent for the Common Benefit Fund in the Storz Morcellator Litigation in the Superior Court of California, of Los Angeles County.

In December 2017, Mr. Gentle was appointed Special Master by the Circuit Court of Duval County, Florida to administer a plastic surgery medical malpractice aggregate settlement with 260 female claimants.

In February 2018, Mr. Gentle was appointed Cy Pres Special Master for the Winston Jefferson County ad valorem tax class settlement case.

In June 2018 Mr. Gentle began to assist lead counsel in the Abilify MDL 2734, to design a claimant payment grid and to facilitate a potential settlement of the case, and in February 2019 he was appointed Extraordinary Damages Award Special Master for the resulting aggregate settlement. The opt-out rate was less than 1%.

In September 2018, Mr. Gentle was appointed Special Master of a personal injury aggregate settlement involving a train derailment in Maryville, Tennessee with CSX and Union Tank as defendants.

In December 2018, Mr. Gentle was appointed Claims Administrator for the U.S. Pipe North Birmingham lead contamination Aggregate Settlement.

In May 2019, Mr. Gentle was appointed Settlement Special Master for a mercury contamination aggregate settlement in Florence, Alabama involving 97 plaintiffs.

Mr. Gentle is a medical monitoring expert in two pending PFOA cases, one in New Jersey and one in upstate New York, being engaged in 2018 and 2019. He administered a PFOA settlement with DuPont in Camden, New Jersey in 2011.

In August 2019, Mr. Gentle was appointed by the Court to administer the aggregate settlement of a bus accident lawsuit in the Calhoun County, Alabama Circuit Court and involving 2 deaths and

44 personal injury claimants.

In November 2019 to January 2020, Mr. Gentle has been appointed Special Master to create grids and to administer three separate aggregate settlements for Bard IVC Filter claimants for three Plaintiffs' law firms.

B. Education

Class Rank	School
4	J.D., University of Alabama School of Law 1981 (Hugo Black Scholarship)
Middle	M.A., Jurisprudence, Oxford University 1980 (Rhodes Scholarship)
Middle	B.A., Honours Jurisprudence, Oxford University 1979 (Rhodes Scholarship)
1	M.S., Summa Cum Laude, University of Miami 1977 (Maytag Fellowship [washing machines])
1	B.S., Summa Cum Laude, Auburn University 1975 (Danforth Scholarship [Purina])

C. Employment Record

June 1992 - Present	Gentle, Turner, Sexton & Harbison, LLC Managing Partner Birmingham, Alabama
September 1991 - June 1992	Miller, Hamilton, Snider & Odom Partner Manager of Birmingham, Alabama Office
January 1987 - September 1991	Schoel, Ogle, Benton, Gentle & Centeno Partner Birmingham, Alabama
December 1985 - January 1987	Law Offices of James L. North Associate Birmingham, Alabama
June 1983 - December 1985	AT&T Senior Staff Attorney Atlanta, Georgia

May 1981 - June 1983	North, Haskell, Slaughter, Young & Lewis Associate Birmingham, Alabama

D. Contact Information

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Katherine Harbison Benson, Esq., Partner

Gentle, Turner, Sexton & Harbison, LLC

Ms. Benson has experience as a transactional attorney, and as an attorney involved in mass tort and class action settlement administration. She has been with the firm for eighteen years.

Ms. Benson provided legal support to Escrow Agent and Partner Edgar C. Gentle with respect to organizational, tax planning, auditing and transactional matters involving the MDL 926 Qualified Settlement Funds, having provided such business support services to all previous MDL 926 Qualified Settlement Funds since 1997, when she began to clerk for the firm, before joining it as an associate.

Since 2005, Ms. Benson has assisted with the administration of the $300 million Tolbert PCB Settlement with Monsanto and Solutia in connection with the administration of a Global Settlement before the Federal District Court for the Northern District of Alabama applicable to approximately 18,000 claimants with respect to PCB contamination of property and PCB personal injury claims.

In 2006, Ms. Benson assisted in the administration of the Culver class action settlement, involving reimbursement of medical expenses not paid for by a medical plan provider. Ms. Benson collected claims data, reviewed medical records, processed claims data, and facilitated payment of claims.

In February of 2008, Ms. Benson began providing legal support to Claims Administrator and Special Master, Edgar C. Gentle, in the 8,500 claimant, Spelter, West Virginia case of Perrine v. DuPont, involving a $380 million Judgment, with a 40 year medical monitoring, a property remediation, and a punitive damages distribution component.

In 2008, Ms. Benson began providing legal support and claims processing for the 10,000 claimant settlement of Cam v. CIGNA, in the Jefferson County, Alabama, Circuit Court.

In 2008 and 2009, Ms. Benson was responsible for processing the ordinary damages claims and facilitating payment for the Bullitt County, Kentucky, Train Derailment Settlement in Shepherdsville, Kentucky, which had approximately 4,000 claimants. She also assisted in the processing of the extraordinary damages claims, including review of medical records, and making payment recommendations.

In 2010, Ms. Benson became involved in the Total Body Formula Litigation, which involved claims of over 240 individuals who were injured when they consumed the Total Body dietary formula. Ms. Benson assisted Special Master Edgar C. Gentle by reviewing medical records, and recommending a payment/injury score for reimbursement, as well as participating in the mediation and partial resolution of the litigation. Ms. Benson is also working with the Special Master and the parties to resolve Medicare, Medicaid and other subrogation claims associated with the litigation.

In 2010, Ms. Benson became involved in the Wayne v. Pharmacia, 3,211 claimant aggregate PCB case in the Jefferson County, Alabama, Circuit Court. Ms. Benson assisted Claims Administrator Edgar C. Gentle, in resolving claimant consent matters involving the settlement, as well as processing claims, and working with the Claims Administrator, the parties and various governmental agencies to resolve Medicare, Medicaid and other subrogation claims associated with the litigation.

In 2011, Ms. Benson became involved in the 4,000 claimant settlement of Rowe v. DuPont, a ground water contamination claims case, in the U.S. District Court in Camden, New Jersey. Ms. Benson has been responsible for designing claim form processing protocols, processing and evaluating claims for payment, and resolution of claim form deficiencies.

In 2012, Ms. Benson began providing legal support to Edgar C. Gentle, the Claims Administrator nominated by the Parties for the $118 million Blackwell, Kay County, Oklahoma Settlement involving soil and house remediation surrounding a former zinc smelter site in Coffey v. Freeport McMoran.

In 2013 and 2014, Ms. Benson worked with Edgar C. Gentle to administer four separate Pfizer Chantix Aggregate Settlements, design the payment matrix, handle claimant appeals, resolve liens, and pay claimants.

In 2015 and 2016, Ms. Benson began working to facilitate three individual aggregate settlements involving individuals who were exposed to contaminated lots of a steroid compounded by the New England Compounding Center during the spring and summer of 2012. Ms. Benson's work in this matter included reviewing medical records, and determining a payment amount under the Court approved grid.

In 2015, 2016, and 2017, Ms. Benson began working with a hip manufacturer and Plaintiffs' Counsel to facilitate three Memphis, Tennessee aggregate settlements involving artificial hips and to resolve related plaintiff liens. Ms. Benson's work in this matter includes reviewing medical records, and recommending a payment/injury score for reimbursement, as well as participating in the mediation and partial resolution of the litigation. Ms. Benson is also working with the parties to resolve Medicare, Medicaid and other subrogation claims associated with the litigation.

In 2016, Ms. Benson began work on the Allen v. A.E. New Pensacola jail fire and explosion case, to facilitate the potential settlement of the case, including working with the Claims Administrator and Parties to develop the claim form and claims processing protocols, reviewing medical records, and processing and evaluating claims for payment.

In October 2016, became involved in the Fulton County, Georgia, Smart v. Brenntag case, assisting the Special Master in carrying out the administration of a chemical spill settlement. Ms. Benson has been responsible for assisting in the design of the claim form processing protocols, processing and evaluating claims for payment, and resolution of claim form deficiencies as well as resolution of Medicare and Medicaid claims.

In 2017, Ms. Benson became involved in the Scottsville, Kentucky, Federal Mogul case, assisting the Special master in carrying out the administration of the aggregate settlement. Ms. Benson has been involved in the design of the claim form processing protocols, evaluating claims for payment, resolution of claim form deficiencies, and resolution of government and private liens.

In September 2017, Ms. Benson began working to assist the Claims Administrator for a GE factory fire in Louisville, Kentucky. Ms. Benson is responsible for assisting in the design of the claim form processing protocols, processing and evaluating claims for payment, and resolution of claim form deficiencies as well as resolution of Medicare and Medicaid claims.

Education:

- J.D., University of Alabama School of Law 1998
- B.S., University of Alabama, *Magna Cum Laude* 1995

Jennifer L. Blankenship, Esq.
Attorney
Gentle, Turner, Sexton & Harbison, LLC

Mrs. Blankenship is an experienced attorney who has worked in mass tort and class action settlement administration and mediation and lien resolution. She has been with the firm for 6 years.

In 2011, Mrs. Blankenship began providing legal support to Edgar C. Gentle, Claims Administrator on the $37.5 Million Jefferson County, Alabama Occupational Tax Refund Case and the Perrine v. DuPont Settlement, when she joined the firm as a paralegal, before joining it as an associate. She assisted with the claims verification process and claimant appeal process.

In addition to her experience in claims verification, heirship issues, and claimant appeals, Mrs. Blankenship has experience in creating the payment and distribution grids for settlements such as the ground water contamination Rowe DuPont Settlement, for approximately 4,000 claimants, and the Blackwell Zinc Smelter Settlement, for more than 2,700 claimants for soil and house remediation surrounding a former zinc smelter site in Coffey v. Freeport McMoran.

In 2013 and 2014, Mrs. Blankenship began working to assist Edgar C. Gentle, Claims Administrator, to facilite four separate Pfizer Chantix Aggregate Settlements, design the payment matrix, handle claimant appeals and resolve liens.

In 2015 and 2016, Mrs. Blankenship began working to facilitate three individual aggregate settlements involving individuals who, primarily, were exposed to three contaminated lots of a steroid (preservative-free methylprednisolone acetate) compounded by New England Compounding Center during the spring and summer of 2012. Mrs. Blankenship's work in this matter includes reviewing medical records, and recommending an injury score to determine a payment allocation for reimbursement under the grid as well as resolution of government and private liens.

In 2015, 2016, and 2017, Mrs. Blankenship began working with a hip manufacturer and Plaintiffs' Counsel to facilitate three Memphis, Tennessee aggregate settlements involving hip implants. Mrs. Blankenship's work in this matter includes reviewing medical records, and recommending an injury score to determine a payment allocation for reimbursement under the grid as well as resolution of government and private liens.

In 2016, Mrs. Blankenship began work on the Allen v. A.E. New Pensacola jail fire and explosion case, to facilitate the potential settlement of the case, including legal support to Edgar C. Gentle, the Claims Administrator in reviewing medical records, recommending an injury classification under the payment grid, and processing and evaluating claims for payment as well as resolution of government and private liens.

In 2017, Mrs. Blankenship began working on the Scottsville, Kentucky, Federal Mogul case, assisting the Claims Administrator in the administration of the aggregate settlement. Mrs. Blankenship has been responsible for assisting in the design of the claim form processing protocols, processing and evaluating claims for payment, and resolution of claim form deficiencies as well as resolution of government and private liens.

In September 2017, Mrs. Blankenship began assisting the Claims Administrator for a GE factory fire in Louisville, Kentucky. Mrs. Blankenship is responsible for assisting in the design of the claim form processing protocols, processing and evaluating claims for payment, and resolution of claim form deficiencies as well as resolution of government and private liens.

Education:

- J.D., Birmingham School of Law, Birmingham, Alabama, 2012
- B.A., University of Alabama at Birmingham, Birmingham, Alabama, 2007

Kathleen C. Clements, Accountant

Gentle, Turner, Sexton & Harbison, LLC

Ms. Clements has more than 20 years of experience in the accounting and finance fields in multiple industries. She began working at Gentle, Turner, Sexton & Harbison, LLC in 2012 to assist in reviewing and processing claims for the Jefferson County, AL Occupational Tax Settlement.

In 2013, she began performing analytical work and Claimant settlement award allocations for the GE CT Scan Litigation. Also in 2013, she began working on Medicare and Georgia Medicaid lien resolution for the Chemtura/Bio-Lab Fire Settlement out of Conyers, GA which consisted of approximately 2,800 Claimants. Global lien resolution agreements with both Medicare and Georgia Medicaid were negotiated for this settlement.

In 2014, she built and maintained a database for and performed all of the lien resolution work for resolution of government liens in the Hydroxycut Settlement which consisted of approximately 500 Claimants. Also in 2014 and 2015, Ms. Clements assisted in the administration of four separate Pfizer Chantix Aggregate Settlements and performed government and private lien resolution for 3 of the 4 settlements.

Since 2014, Ms. Clements has been performing lien resolution work for multiple settlements. Her work on these cases included Claimant support and correspondence and heavy lien reduction negotiations for the following cases:

- Both government and private lien resolution for 3 settlements for metal-on-metal hip implants; total of approximately 550 Claimants
- Government lien resolution for a nationwide diet supplement settlement; total of approximately 170 Claimants
- Government lien resolution for a food contamination settlement; total of approximately 35 Claimants to date (this settlement is ongoing)
- Both government and private lien resolution for settlements involving compounded lots of steroids that were contaminated with fungal meningitis; total of approximately 40 Claimants to date (this settlement is ongoing). In one particularly egregious case, Ms. Clements successfully negotiated a $250k reduction in a hospital's lien due to the hospital's unlawful billing practices.
- Government lien resolution for a settlement involving an infertility drug; total of approximately 250 Claimants
- Government lien resolution for a GE factory fire settlement; total number of Claimants was more than 5,200
- Both government and private lien resolution for a settlement involving a jail fire and explosion in Pensacola, FL; total number of Claimants is approximately 680

Education:

- MAc, University of Alabama at Birmingham, Birmingham, AL 1999
- B.S., Auburn University, Auburn, AL 1994

EXHIBIT E

GOVERNMENT BENEFITS QUESTIONNAIRE

GENTLE, TURNER, SEXTON & HARBISON, LLC
501 RIVERCHASE PARKWAY EAST, SUITE 100
HOOVER, ALABAMA 35244
TOLL FREE (800) 345-0837 • LOCAL (205) 716-3000 • FAX (205) 716-2364
OUR FILE NO. 6626-1

I. PERSONAL INFORMATION

– If you are completing this form on behalf of a Claimant (as Parent, Guardian, Representative, POA, GAL, etc.), **complete this entire form using information for the Claimant and attach a copy of the documentation designating you as such. PLEASE WRITE LEGIBLY.**

Name: _____ Date of Birth: ____/____/____
(First) (M.I.) (Last) mm/dd/year

Current Address: _____

City: _____ State: _____ Zip: _____

Full SSN: _____ Telephone: (_____) _____ Mobile: (_____) _____
(Required)

Gender: **M** ☐ **F** ☐

Is the Claimant deceased? YES ☐ **NO** ☐ If yes, state your relationship to Claimant: _____

II. SETTLEMENT INJURY INFORMATION

Date of your **FIRST** exposure: _____ Date of your **LAST** exposure: _____

****PROVIDE ALL DOCUMENTATION YOU HAVE OF YOUR FIRST EXPOSURE AND LAST EXPOSURE AS REQUIRED UNDER THE POD****

Date of onset of your first symptoms related to your settlement injury: _____

City, State and County in which your exposure occurred: _____

Briefly describe your injuries related to this case as diagnosed by a doctor: _____

_____

_____

_____

III. GOVERNMENT BENEFIT INFORMATION

A. Are you eligible for ***MEDICARE (federally-sponsored)*** Parts A &/or B benefits (please answer regarding your eligibility to receive Medicare benefits even if you have a Medicare replacement plan in effect)? **YES** ☐ **NO** ☐
(If you are 65 or older or have been on disability for more than 24 consecutive months, you are usually automatically eligible.)

i. On what date did you become eligible for Medicare? _____

ii. Please list your Medicare number (HICN or MBI): _____

********PLEASE ATTACH A COPY OF YOUR MEDICARE CARD, IF AVAILABLE********

B. At the time of your **FIRST** date of exposure, were you eligible for or receiving ***MEDICAID (state sponsored, needs-based)*** benefits? **YES** ☐ **NO** ☐
(Answer **YES** even if benefits were **not** paid)(this includes Managed Care Organizations/Providers under the state Medicaid program)

i. Please provide the State that you receive your Medicaid benefits from? _____
ii. Please list your Medicaid number: _____
iii. If known, list your Medicaid Managed Care Organization: _____

GOVERNMENT BENEFIT INFORMATION, CONT.

C. At any time after your **FIRST** date of exposure, were you eligible for or did you receive ***MEDICAID (state sponsored, needs-based)*** benefits (Please list **ALL** States if more than one)? **YES** ☐ **NO** ☐
(Answer **YES** even if benefits were **not** paid)(this includes Managed Care Organizations/Providers under the state Medicaid program)

i. Please provide the State that you receive your Medicaid benefits from?_____
ii. Please list your Medicaid number:_____
iii. If known, list your Medicaid Managed Care Organization: _____

*********PLEASE ATTACH A COPY OF YOUR MEDICAID CARD(S)*********

D. Have your EVER received ***Military medical insurance (Tricare or CHAMPUS)***? **YES** ☐ **NO** ☐

If YES, are you the Sponsor or a Dependent? (circle one) **SPONSOR** **DEPENDENT**

If YES, in what branch of the Armed Forces did you or the sponsor serve? _____

Sponsor Name and ID number: _____

Health program plan name (Prime, For Life, etc.): _____

E. Are you eligible to receive **ANY** medical treatment (not just service connected treatment) from a ***Veterans Administration ("VA") hospital or any other VA medical facility***? **YES** ☐ **NO** ☐

Do you have CHAMPVA? **YES** ☐ **NO** ☐

If YES to either question above, please list the names and locations (city and state) of all VA treatment facilities from which you have received ANY medical treatment, even if the medical treatment is not related to this case (attach additional pages, if needed):

_____

_____

_____

_____

_____

F. Do you have any other type of known ***government*** medical liens or known ***government*** medical insurance providers not listed on this questionnaire previously (i.e Indian Health Services)? **YES** ☐ **NO** ☐

If YES, please list the lienholder or government medical insurer and phone number:

_____

_____

_____

IV. MEDICARE PART C AND PART D PRIVATE MEDICAL BENEFIT INFORMATION

A. Have you ever had **Medicare Part C** health insurance at the time of or after your settlement-related personal injury/exposure? **YES** ☐ **NO** ☐
(This applies for Medicare Part C and ANY Medicare Advantage or Medicare supplement plan.)

If Yes, complete the following: (if you had more than 1 other insurance company, please list them on a separate sheet and attach)

Full name of your Medicare Part C company: _____

Member ID #: _____

Group #: _____ Policy #: _____

Insurance Company's phone #: (may be found on the back of your insurance card): _____

Insurance Company's Address: _____
Street

_____
City State Zip

*******PLEASE ATTACH A COPY OF THE FRONT & BACK OF YOUR INSURANCE CARD(S)*******

B. Have you ever had **Medicare Part D** health insurance at the time of or after your settlement-related personal injury/exposure? **YES** ☐ **NO** ☐
(This applies for Medicare Part C and ANY Medicare Advantage or Medicare supplement plan.)

If Yes, complete the following: (if you had more than 1 other insurance company, please list them on a separate sheet and attach)

Full name of your private insurance company: _____

Member ID #: _____

Group #: _____ Policy #: _____

Insurance Company's phone #: (may be found on the back of your insurance card): _____

Insurance Company's Address: _____
Street

_____
City State Zip

*******PLEASE ATTACH A COPY OF THE FRONT & BACK OF YOUR INSURANCE CARD(S)*******

If you have had additional Medicare Part C and/or Part D medical insurers since your date of injury that you have not listed in questions A or B above, please attach additional page(s) with information for any additional medical insurers you've had since your exposure date AND provide a copy of the front and back of your insurance card(s) for those insurers. You are responsible for providing accurate information for any medical insurers you've had since your date of exposure.

V. RELEASE AND SIGNATURE

By signing below, you agree to the release of the information given, and your name, address, Social Security Number, and date of birth to the Private and/or Governmental Agencies referenced in Parts III, IV and V above. It is your responsibility to notify us if any of your benefit information changes or needs to be supplemented. **The undersigned hereby swears under penalty of perjury that all of the information provided herein is true and accurate.** Your signature if an adult; Parent or Guardian's Signature if a Minor; or Personal Representative's Signature if Claimant is incapacitated or deceased:

_____ Date: _____/_____/_____

Claimant's Signature
(or Representative's Signature)

If you are signing this document as a Representative, please state your relationship to the Claimant:_____

****If you have signed this document as a Representative, you must attach documents designating you as such.****

PLEASE MAKE SURE THAT YOU COMPLETE & RETURN ALL PAGES OF THIS FORM. MISSING OR ILLEGIBLE INFORMATION AND/OR PAGES WILL DELAY THE PROCESSING OF YOUR CLAIM.

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Claimant Name: _____ Date: _____

Date of Birth: _____ SSN: _____

1. The following individual or organization is authorized to make the disclosure **(if you are unsure of medical insurance/financial institution's EXACT legal name, leave blank and we will complete this for you):**

   _____

2. The type and amount of information to be used or disclosed as follows:

   The entire record, including but not limited to: any and all medical records, mental health records, psychological records, psychiatric records, problem lists, medication lists, lists of allergies, immunization records, history and physicals, discharge summaries, laboratory results, x-ray and imaging reports, medical images of any kind, video tapes, photographs, consultation reports, correspondence, itemized invoices and billing information, and information pertaining to Medicaid or Medicare eligibility and all payments made by those agencies **(if unsure of EXACT dates per the complaint or demand, leave blank and we will complete this section for you).**

   Dates of Services: From: _____ To: _____

3. I understand that the information in my health records may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, and treatment for alcohol and drug abuse.

4. This information may be disclosed to and used by the following individual or organization:

   GENTLE, TURNER, SEXTON & HARBISON, LLC
   501 Riverchase Parkway East, Suite 100
   Hoover, Alabama 35244
   (p) 205-716-3000 (f) 205-716-2364

5. I understand I have the right to revoke this authorization at any time. I understand if I revoke this authorization, I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will expire upon the settlement of my claim.

6. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to assure treatment. I understand that my Health Plan will not condition its payment activities in connection with my claims, or my enrollment in my Health Plan, or my eligibility for benefits upon my giving this authorization. I understand I may inspect or copy the information to be used or disclosed, as provided in CFR 1634.524. I understand any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact the HIM director, privacy officer, or other release of information employee of the above named healthcare provider.

_____ _____

Patient or Legal Representative

Relationship to Patient (If signed by Legal Representative)

MEDICARE PROOF OF REPRESENTATION

Sign below if you, the Medicare beneficiary, want to inform the Centers for Medicare & Medicaid Services (CMS) that you have given another individual the authority to represent you and act on your behalf with respect to your claim for liability insurance, no-fault insurance, or workers' compensation, including releasing identifiable health information or resolving any potential recovery claim that Medicare may have if there is a settlement, judgment, award, or other payment. Your representative must also sign that he/she has agreed to represent you.

Type of Medicare Beneficiary Representative (Check one below and then print the requested information):

( ) Individual other than an Attorney:
(X) Attorney*
( ) Guardian*
( ) Conservator*
( ) Power of Attorney*

Name: Edgar C. Gentle, III, Esq. and Katherine A. Benson, Esq.
Relationship to Medicare Beneficiary: Lien/Settlement Administrator
Firm or Company Name: Gentle, Turner, Sexton & Harbison, LLC
Address: 501 Riverchase Parkway East, Suite 100
Hoover, AL 35244
Telephone: (p) 205-716-3000 (f) 205-716-2364

Medicare Beneficiary Information and Signature/Date: **For this document, the Claimant who is involved in the settlement is the Beneficiary. This does NOT mean a spouse or other heir/representative:**

Please complete numbers 1-4 below only:

1. Beneficiary's Name
Please print exactly as shown on your Medicare card: _____

2. Beneficiary's Medicare Number (number on your Medicare card): _____

3. Date of Illness/Injury for which the beneficiary has filed a liability insurance, no-fault insurance or workers' compensation claim: _____
(if you are unsure of the exact date of injury as listed on the complaint or demand, please leave this blank and we will complete it for you.)

4. Beneficiary Signature: _____ Date signed: _____

****Due to the recent nationwide change in the Medicare number system, please provide a copy of the front of your Medicare card. Failure to provide your current Medicare number could result in a delay in processing your case.****

For Lien Administrator's Use Only – DO NOT WRITE OR SIGN BELOW THIS LINE:

Representative Signature/Date:

Representative's Signature: _____ Date signed: _____

Our File No.: _____